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2005 PROPOSED MEDICARE CONDITIONS OF PARTICIPATION FOR HOSPICE PROGRAMS WITH REQUEST FOR COMMENTS

File Code CMS-3844-P

COMMENTS SUBMITTED FROM *THE CAROLINAS CENTER FOR HOSPICE AND END OF LIFE CARE*-- HOSPICE FACILITY-BASED WORKGROUP

P.O. BOX 4449
CARY, NORTH CAROLINA 27519

2005 CMS PROPOSED COPS	*REQUEST FOR COMMENTS*
§ 418.2 Scope of the part.	
§ 418.3 Definitions	
Attending physician means a— (1) (i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or (ii) Nurse practitioner who meets the training, education and experience requirements as the Secretary may prescribe; and (2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.	
Bereavement counseling means emotional, psychosocial, and spiritual support and services provided after the death of the patient to assist with issues related to grief, loss, and adjusting.	
Cap period means the 12-month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in §418.309.	
Clinical note means a notation of a contact with the patient that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical or emotional condition.	

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Drug restraint means a medication used to control behavior or to restrict the patient's freedom of movement, which is not a standard treatment for a patient's medical or psychiatric condition.	
Employee means a person who works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf, or if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice or is a volunteer under the jurisdiction of the hospice.	
Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.	
Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary team to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.	
Licensed professional means a licensed person sanctioned by the State in which services are delivered, furnishing services such as skilled nursing care, physical therapy, speech-language pathology, occupational therapy, and medical social services.	
Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.	
Physical restraint means any manual method or physical or mechanical device, material, or equipment attached to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.	**"equip. attached or adjacent to the pt's body" would be approp. addition. Clinical judgement to use "restraint" needs to be allowed for sx management & safety as addressed in 418.110/o**
Progress note means a written notation, dated and signed by any person providing services, that summarizes facts about the care furnished and the patient's response during	

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a given period of time.	
Representative means an individual who has the authority under State law (whether by statute or pursuant to an appointment by the courts of the State) to authorize or terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill patient who is mentally or physically incapacitated. This may include a legal guardian.	
Restraint means either a physical restraint or a drug used as a restraint.	
Satellite location means a Medicare-approved location from which the hospice provides hospice care and services within a portion of the total geographic area served by the hospice location issued the provider agreement number. The satellite location is part of the hospice and shares administration, supervision, and services in a manner that renders it unnecessary for the satellite location to independently meet the conditions of participation as a hospice.	
Seclusion means the confinement of a person in a room or an area where a person is isolated and physically prevented from leaving.	
Terminally ill means that the patient has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.	

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§ 418.52 Condition of participation: Patient's rights.	
(a) Standard: Notice of rights.	
(b) Standard: Exercise of rights and respect for property and person.	
(c) *Standard: Pain management and symptom control.*	
(d) *Standard: Confidentiality of clinical records*	
(e) *Standard: Patient liability.*	
§ 418.54 Condition of participation: Comprehensive assessment of the patient.	
(a) *Standard: Initial assessment.*	
(b) *Standard: Time frame for completion of the comprehensive assessment.*	
(c) *Standard: Content of the comprehensive assessment.*	
(d) *Standard: Update of the comprehensive assessment.*	
(e) *Standard: Patient outcome measures.*	
§ 418.56 Condition of participation: Interdisciplinary group care planning and coordination of services.	
(a) *Standard: Approach to service delivery.*	
(b) *Standard: Plan of care.*	

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(c) *Standard: Content of the plan of care*	
(d) *Standard: Review of the plan of care.*	
(e) *Standard: Coordination of services..*	
§ 418.58 Condition of participation: Quality assessment and performance improvement.	
(a) *Standard: Program scope.*	
(b) *Standard: Program data.*	
(c) *Standard: Program activities.*	
(d) *Standard: Performance improvement projects.*	
(e) Standard: Executive responsibilities	
§418.60 Condition of participation: Infection control.	
(a) *Standard: Prevention*	
(c) *Standard: Education.*	
§ 418.62 Condition of participation: Licensed professional services.	
§ 418.64 Condition of participation: Core services.	
(a) *Standard: Physician services.*	
(b) *Standard: Nursing services.*	
(c) *Standard: Medical social services.*	
(d) *Standard: Counseling services* (i) *Bereavement counseling.* (2) *Nutritional counseling.* *(3) Spiritual counseling.*	
§ 418.66 Condition of participation: Nursing services—Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.	
Non-Core Services **§ 418.70 Condition of participation: Furnishing of non-core services.**	
§ 418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.	
§ 418.76 Condition of participation: Home health aide and homemaker services.	
(a) *Standard: Home health aide qualifications.*	
(b) *Standard: Content and duration of home health aide classroom and supervised practical training.*	
(c) *Standard: Competency evaluation.*	
(d) *Standard: In-service training.*	
(e) *Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training.*	
(f) *Standard: Eligible training organizations.*	
(g) *Standard: Home health aide assignments and duties.*	
(h) *Standard: Supervision of home health aides.*	
(i) *Standard: Individuals furnishing Medicaid personal*	

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care aide-only services under a Medicaid personal care benefit.	
(j) *Standard: Homemaker qualifications.*	
(k) *Standard: Homemaker supervision and duties.*	
§ 418.78 Conditions of participation: Volunteers.	
(a) *Standard: Training.*	
(b) *Standard: Role.*	
(c) *Standard: Recruiting and retaining.*	
(d) (d) *Standard: Cost saving.*	
(e) *Standard: Level of activity.*	
§ 418.100 Condition of participation: Organization and administration of services.	
(a) *Standard: Serving the hospice patient and family.*	
(b) *Standard: Governing body and administrator*	
(c) *Standard: Services.*	
(d) *Standard: Continuation of care.*	
(e) *Standard: Professional management responsibility.*	
(f) *Standard: Hospice satellite locations.*	
(g) *Standard: In-service training.*	
§ 418.102 Condition of participation: Medical director.	
(a) *Standard: Initial certification of terminal illness.*	
(b) *Standard: Recertification of the terminal illness.*	
(c) *Standard: Coordination of medical care.*	
§ 418.104 Condition of participation: Clinical records.	
(a) *Standard: Content.* Each patient's record must include the following:	
(b) *Standard: Authentication.*	
(c) *Standard: Protection of information.*	
(d) *Standard: Retention of records.*	
(e) *Standard: Discharge or transfer of care.*	
(f) *Standard: Retrieval of clinical records.*	
§ 418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.	
(a) *Standard: Administration of drugs and biologicals..*	
(b) *Standard: Controlled drugs in the patient's home.*	
(c) *Standard: Use and maintenance of equipment and supplies*	
§ 418.108 Condition of participation: Short-term inpatient care.	**The provision of short-term inpatient must include provision of that care for crises of a psychosocial/family/caregiver nature**
(a) *Standard: Inpatient care for symptom management and pain control.*	**Due to the nature of the care, general inpatient level of care must require 24 hour nursing onsite at the RN level due to the need for critical thinking skills**

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(b) *Standard: Inpatient care for respite purposes.*	**Respite care should be redefined as a routine level of care and therefore not requiring 24 hour nursing onsite at the RN level**
(c) *Standard: Inpatient care provided under arrangements.*	
(d) *Standard: Inpatient care limitation.*	**We request that respite days be removed from the count of GIP days (if changed from respite inpatient to routine respite care)**
(e) *Standard: Exemption from limitation.*	
§ 418.110 Condition of participation: Hospices that provide inpatient care directly.	**Clarify that subsequent standards in 418.110 applies to hospice owned facilities, not contracted nursing facilities**
(a) *Standard: Staffing..*	
(b) *Standard: Twenty-four hour nursing services.*	**24hr RN on site at GIP, RN on call for respite/routine**
(c) *Standard: Physical environment.*	**Equip. failure reporting only if sentinel event? required by whom & to whom? (ii) may be from Safe Medical Device Act**
(d) *Standard: Fire protection.*	
(e) *Standard: Patient areas*	
(f) *Standard: Patient rooms.*	**This proposed requirement is not seen as a burden**
(g) *Standard: Toilet/bathing facilities.*	
(h) *Standard: Plumbing facilities.*	
(i) *Standard: Infection control.*	
(j) *Standard: Sanitary environment..*	
(k) *Standard: Linen.*	
(l) *Standard: Meal service and menu planning.*	
(m) *Standard: Pharmaceutical services.*	**Agree to cross ref. 418.106 as whole agency.**
(n) Pharmacist.	**(n)(2)(iii) include pt identified caregiver**
(o) *Standard: Seclusion and restraint.*	**This new standard needs to allow for the management of the safety of the resident and the staff. There must be language that speaks to common symptom management in a terminally ill patient that might be construed as chemical restraints in other healthcare settings. The language in this standard appears to apply to hospital settings—the hospice inpatient facility is not a hospital or a long-term nursing facility.** **"control behavior" must be delineated from methods needed to ensure comfort/freedom from distress for the hospice patient & safety of the hospice patient & caregivers.** **Allow for hospice documentation to support treatment options for the patient & family.** **Examples needing appropriate hospicereatment that may be misconstrued as restraint: terminal restlessness, existential distress, intractable pain, dementia, anxiety, brain disease** **Examples of meds used: lorazepam, haloperidol, midazolam, chlorpromazine** **(O)(3)(ii)(c):MD eval w/in 1 hr: could be burdensome & unnecessary in hospice owned facility.**
§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities.	
(a) *Standard: Resident eligibility, election, and duration*	

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of benefits.	
(b) *Standard: Professional management.*	
(c) *Standard: Core services.*	
(d) *Standard: Medical director.*	
(e) *Standard: Written agreement.*	
(f) *Standard: Hospice plan of care.*	
(g) *Standard: Coordination of services.*	
(h) *Standard: Transfer, revocation, or discharge from hospice care.*	
(i) *Standard: Orientation and training of staff.*	
§ 418.114 Condition of participation: Personnel qualifications for licensed professionals. (a) *General qualification requirements.*	**If the issue is BSW vs MSW it is felt that this is not an issue, experience is the key and a BSW might be sufficient.**
(b) Personnel qualification for physicians, speech-language pathologist, and home health aides.	
(c) *Personnel qualifications when no State licensing, certification or registration requirements exist.*	
(d) *Standard: Criminal background checks.*	**This requirement is not seen as a burden but a must – leave it in**
§ 418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to health and safety of patients.	
(a) *Standard: Licensure of staff.*	
(b) *Standard: Multiple locations*	
(c) *Standard: Laboratory services.*	
§ 418.200 [Amended]	
§ 418.202 [Amended]	

Subpart G – Payment for Hospice Care	*2005 CMS PROPOSED COPS*
	No changes are proposed to this Subpart at this time.

Subpart H – Coinsurance	*2005 CMS PROPOSED COPS*
	No changes are proposed to this Subpart at this time.

Caring Community Hospice
Of Cortland

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Cortland, N.Y. 13045
(607) 753-9105

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3844-P
P.O. Box 8010
Baltimore, MD 21244-8010

Dear Sir or Madam: July 22, 2005

Thank you for the opportunity to comment on the Medicare and Medicaid programs: Hospice Conditions of Participation: Proposed Rule published on May 27, 2005 in the Federal Register, and for taking our comments under consideration. As a smaller rural program, our concerns are just as important as larger programs, since we all have to live under the same Conditions. We believe that a lot of work went into these proposed revisions, and most are very workable, indeed are many of the same things we are already doing to a large extent. Here are the few that cause us some concern:

Section 418.3 Definitions

We request the following changes in this section:

1. The definition for *Drug restraint*: consider amending as follows: means a medication used to control behavior or to restrict the patient's freedom of movement, "which is not a standard hospice treatment or not requested by the patient or the patient's surrogate." Hospice commonly uses medications such as Haldol or Ativan to control symptoms, which are considered a drug restraint in other settings. The issue here is patient's rights. Our concern is that in trying to protect patient's rights, this will actually restrict a hospice patient's right to control end-of-life symptoms. Hospice provides most care in the patient's home where there would be no benefit to hospice staff to have the patient restrained. Dying patients also have the right to have troubling symptoms managed effectively. Whether a patient/family choose to actually use an ordered medication (after full education re: dose, use, side effects) is entirely up to them. **That is NOT a restraint.**

Section 418.52 Condition of Participation: Patient's Rights

1. Section (a) (3) "tracking" of drugs - Prescriptions are dispensed to the patient and are their property, unlike in an institution, where they are owned and fully under the control of the facility. It will be virtually impossible for hospice to "track" drugs when they are not under our complete control. We already do limited prescription fills, know when refills are due, and count narcotics remaining at death. That's as far as we can "track". Plus, we can't be held responsible for narcotics dispensed

that are NOT supplied by the hospice, since they are not related to the terminal diagnosis. We have no control over their dispensing, refilling, etc.

Section 418.54 Condition of Participation: Comprehensive Assessment

Section (a):

- **We have a problem with the 24 hour rule (we believe you mean "physician certification" rather than "physician order"?). This requirement is problematic for many reasons:**

1) If you leave this as "order", ANY physician might call in a referral, but not be willing to act as attending physician and therefore would not be the certifying physician. (Surgeons are notorious for this- they wash their hands after they make a referral call.) So, with this wording, we'd have to go and assess whether or not we have a certifying physician, without being able to admit. . . .a waste of time and <u>very unkind</u> to a patient!
2) The 24 hour rule leaves absolutely no leeway for patient/ family need or preference- something hospice is all about in the first place. It is very common to try to set up a home visit time, only to have the patient want to wait for her daughter to be available at a later time, well beyond the 24 hours. This is NOT the same as a home care admission where you can walk in and admit. Here we are required to give FULL explanation of the waiver of their standard Medicare, election of palliative comfort care, etc. There are MANY ramifications when a family member (who wasn't at the initial assessment and program explanation) hauls Mom off to the specialist again after hospice admission (and (s)he's not the attending physician and doesn't know patient is in hospice), who does an MRI or CT scan. . . . . guess who gets the bill? Admission consents clearly state the patient agrees all tests related to the hospice diagnosis must be preapproved by the hospice to be paid. In this scenario, hospice doesn't pay, Medicare refuses to pay, and the 87 yr old patient who forgot that requirement gets a bill for thousands of dollars, all because we didn't have that family member on board with the program. How the program is explained up front is CRUCIAL. . .that's why we try to get as many family members as possible (that the patient wants involved) at that initial visit.
3) We do weekend admissions when we know about them on a Friday, have enough medical information to review, have a certifying physician, and can explain the program and consents to the patient/family (done by a primary hospice RN). Our on-call nurse then goes out to do the assessment and start care. We have exactly two primary RNs in our program. Otherwise, we have on-call nurses to respond to patients' needs after hours. There is too much explanation of the program and consents in an admission assessment to teach an on-call nurse to do. . . . . .to say nothing of the fact that the full program explanation process is lengthy, followed by the "assessment of needs". We can't tie up an on-call nurse who must respond to other patients in a timely manner. **We have no idea how we could meet this requirement without paying another nurse to be on standby for admissions only. That would devastate our nursing salary budget.**

Doctor's offices are not routinely open in our area on the weekends. We have had exactly one referral in the past year that came in on a Saturday- it came at 10 pm on Saturday night from a surgeon in an ER. So, with your requirement, we would have had no medical information (other than the little the ER had) to review, we would have no promise of a certifying physician (surgeon would not act as attending), but we would still be forced to have gone out to the patient by 10 pm on Sunday evening to do the initial "assessment of needs". And if the patient had not been Medicare or Medicaid, it is likely we would have no idea what to tell them about their insurance because their insurance offices would be closed (another requirement of yours . . patients have the right to know their financial liability prior to service delivery). So what good is the "initial assessment of needs" when we precious little information we can tell them AND we could not have admitted without a certifying physician and more information?

We believe your intent was to make sure that hospices are responding in a timely manner to referrals. Let me assure you that our small rural hospice (whose doctor's offices are closed on weekends) is just as timely as large urban hospices (whose doctor's offices are open on weekends making referrals, and whose hospices have separate admission teams working full time on the weekends.) How do we know this? Our median length of stay in 2003 was 18 days, in 2004,was 17.5 days. The median length of stay for all of New York State hospices for 2003 (latest data available) was 18 days. We are admitting just as timely as large hospices with offices open on weekends.

The 24 hour requirement makes no sense and places an undue unnecessary burden on small rural hospices, which we don't believe was your intent. Large urban hospices and state hospice associations probably will not even comment on this because it does not affect them, but for us, this is very problematic and very costly to implement for the one time a year it might come up.

Section (c) Content of the comprehensive assessment- It needs to be recognized that hospice is dependent upon the patient/family/physican regarding the use of drugs other than for the terminal illness. Hospice cannot be held responsible for being aware of drugs that hospice is not informed of by the patient, family, physician or other health care provider.

Section (d) Standard: Update of the comprehensive assessment.

- **Please consider "every 14 days" be changed to "every two weeks," or "15 days" to provide the leeway needed for holidays and emergencies.** This is yet another burden that home care agencies do NOT have. We need some leeway here. Otherwise, a future surveyor will take out a calendar, count off 14 calendar days, and fault a hospice for being one day early once and not sticking with that revised schedule from then on.

(d) Review of plan of care – recommend 14 days be changed to two weeks or 15 days. **(Same rationale as already discussed previously.)**

(h) i. change every 14 days to every two weeks, **(same rationale as discussed previously)** and change 28 days to 60 days to be consistent with NYS statute.

Section 418.102 Condition of Participation: Medical Director

1. **Section (c)** Medical Directors are not the best choice to direct the hospice's quality assessment and performance improvement program. Seeing how it works in other institutions (hospitals, NFs), the Medical Director delegates all the actual planning, analysis and work to others, then signs off on the results. We sincerely do not believe that is your intent. Please rethink this issue. Medical Directors know medical issues. They are not as informed overall when it comes to other programatic quality issues (and there are many). They are definitely NOT the best to oversee this important piece of hospice.

Section 418. 104 Condition of Participation: Clinical Records

1. Section (e) – please drop the requirement for hospice to provide a "copy of the clinical record" to the patient's attending physician in the case of a revocation or discharge. The discharge summary is more than adequate. Under HIPAA, we really only can supply the "minimum necessary". What is the "entire medical record" needed for? If it is, they can request the parts they need. **The purpose of a discharge summary is to ensure coordinated continuing care by the next provider.** That is the intent of this reg. Doctors will be steaming mad if they start to receive volumes of papers they don't need and did not request. This requirement makes no sense.

Section 418.106 Condition of Participation: Drugs, Controlled Drugs and Biologicals

1. **Section (b)** Hospice is not legally able to collect controlled drugs in a patient's home – it is illegal to transport a controlled substance without a prescription and this would typically be done when the patient has died so the prescription is no longer valid. The word "collecting" MUST BE REMOVED. The term tracking is also of concern. **We have previously discussed this.**

Item (o) *Standard: Restraint and seclusion.*
As noted in the previous section "Definitions" We have great concern over the potential impact on end-of-life care when use of a medication to control some symptoms such as terminal agitation or restlessness, is perceived as imposition of a chemical restraint. It is not. That is standard acceptable hospice symptom management. **Suggested change** for inclusion in (o)(1) is the addition

after"…normal access to ones' body" is "**Bed rails are not included in this definition of restraint if used for the safety of the patient or to assist the patient in independent functioning.**"

418.110 Conditions of Participation: Hospices that provide hospice care to residents of a SNF/ICF, MR or other facilities.

Does this condition match the requirements that will be proposed for nursing homes? They need to be match and be very clearly in nursing home regs.

(c) *Standard: Medical Director*

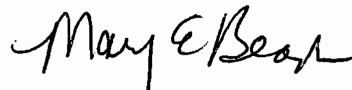
Good communication between hospice medical director through the hospice team (generally the hospice nurse) works well for most NF patients most of the time. It is not realistic nor necessary for medical director to speak directly with a NF medical director UNLESS there is a problem. That's the current practice. Physicians are incredibly busy. Why are you mandating direct communication on each and every patient? Why is this any different than a patient we serve at home with an attending doctor? To be consistent, you would have to mandate that the hospice medical director directly call each and every attending physician for a home care case, too. This requirement makes no sense for any case- NF or home care.

(d) *Standard: Hospice Plan of care*

Item (3) regarding the 14-day requirement for care plan review. Suggestion that this be changed to 15 days to better synch with the existing certification schedule.

Thank you again for your consideration of all our comments. We appreciate the time and effort involved in making these revisions. We all want the same thing. Quality care for hospice patients and families.

Sincerely,



Mary E. Beach
Hospice Director

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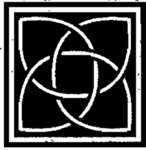


Texas Non-Profit Hospice Alliance

July 22, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Att: CMS-3844-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: File code CMS-3844-P

To Whom It May Concern:

The Texas Non-Profit Hospice Alliance (TNPHA) represents twenty (20) non-profit hospices serving the majority of the population of Texas. We would like to submit the attached comments on the proposed revision of the Conditions of Participation for hospice providers and would appreciate your review and consideration of them.

We appreciate the time and work that has gone into the proposed revisions and look forward to reviewing any proposed changes in a second comment period.

Thank you for your consideration of these comments.

In the Spirit of Hospice-
Respectfully,

Edd Hess, President
Texas Non-Profit Hospice Alliance
c/o Cypress Basin Hospice
207 W. Morgan Street
Mount Pleasant, Texas 75455
(903) 577-1510

Attachments:
One original and two copies

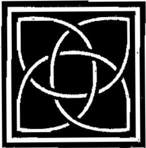
Submitted on Behalf of the Following Members of the Texas Non-Profit Hospice Alliance:

VNA and Hospice of South Texas
San Antonio, Texas

Houston Hospice
Houston, Texas

Hospice of Midland
Midland, Texas

Christus Spohn Hospice
Corpus Christi, Texas



Texas Non-Profit Hospice Alliance

Hospice of Wichita Falls
Wichita Falls, Texas

Home Hospice of Grayson County
Sherman, Texas

Hospice of South Texas
Victoria, Texas

Community Hospice of Texas
Fort Worth, Texas

Hospice of Texarkana
Texarkana, Texas

Hospice of San Angelo
San Angelo, Texas

Greater Hill Country Hospice
Fredericksburg, Texas

Hospice Team Care
Texas City, Texas

Lakes Area Hospice
Jasper, Texas

Hospice of East Texas
Tyler, Texas

Hospice of Brazos Valley
Bryan, Texas

Hospice Austin
Austin, Texas

Cypress Basin Hospice
Mount Pleasant, Texas

Hospice of El Paso
El Paso, Texas

Hendrick Hospice Care
Abilene, Texas

Hospice of Deep East Texas
Nacogdoches, Texas

CMS-3844-P

2005 Proposed COPs	Comments by Texas Non-Profit Hospice Alliance (Alliance)
418.52 Condition of Participation: Patient's Rights	
(a) Standard: Notice of rights: (1) The hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care.	**The hospice must provide the patient or representative with <u>verbal</u> notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care. The hospice must provide the patient or representative with <u>written</u> notice of the patient's rights and responsibilities in the predominant language(s) of the hospice's service area during the initial evaluation visit in advance of furnishing care.** *Rationale: In some communities, there are hundreds of dialects and it will be extremely costly and expensive to translate these documents into all languages & dialects. This requirement will become a significant barrier to accessing hospice for these patients. Verbal translation occurs now and works well and does not deny patients access to hospice care.*
(3) The hospice must inform the patient and family of the hospice's drug policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances.	**<u>Delete requirement related to informing patient and family of hospice's drug policies and procedures upon admission.</u>** *Rationale: We believe that patients and families are already overwhelmed at the time of admission and this information should ~~be presented to the patient and family by the appropriate member~~ of the IDT after, not during, admission.*
(b) Standard: Exercise of rights and respect for property and person.	**The Alliance recommends that CMS consider using the patient rights requirements as defined in the Home Health**

	COPs at 484.10 for the hospice COPs, which we believe are more appropriate to the hospice/home environment.
(4) The hospice must- (i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at least 5 working days of the incident, and immediately to the hospice administrator.	**(4) The hospice must-** **(i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within 5 working days of the incident, and immediately to the hospice administrator.** *Rationale: We believe that "within 5 working days" is less confusing.*
(e) Standard: Patient liability. Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.	**Before care is initiated, the patient must be informed, ~~verbally and in writing, and in a language that he or she can understand,~~ of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.** *Rationale: In some communities, there are hundreds of dialects and it will be extremely costly and expensive to translate these documents into all languages & dialects. This requirement will become a significant barrier to accessing hospice for these patients. Verbal translation occurs now and works well and does not deny patients access to hospice care.*
418.54 Condition of Participation: Comprehensive assessment of the patient.	
(a) Initial assessment: The hospice registered nurse must make an initial assessment visit within 24 hours after the hospice receives a physician's admission order for care	**The hospice registered nurse must make an initial assessment visit within <u>48 hours</u> after the hospice receives a physician's admission order for care (unless ordered otherwise by the**

(unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.	**physician <u>or requested otherwise by the patient and/or family</u>), to determine the patient's immediate care and support needs.** *Rationale: We believe that while most hospices make the initial assessment visit within 24 hours, this standard is too restrictive and will result in deficiencies when the hospice occasionally is unable to make the initial assessment visit within 24 hours.*
(b) The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.	**The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than <u>7 calendar days</u> after the patient elects the hospice benefit.** *Rationale: We believe that many patients and families will object to having 4 different people contact them within 4 days of initiating hospice care to complete the comprehensive assessment. We have a 7 day standard in Texas now and we often receive comments from families that it is, "raining hospice people".* **<u>The Alliance recommends that CMS not prescribe WHO must complete the comprehensive assessment, but instead prescribe WHAT must be assessed, namely the patient/family's physical, emotional, social and spiritual needs.</u>**
	~~Rationale: Many patients and families refuse hospice services~~ from a social worker and chaplain/counselor, and emotional, social and spiritual needs are assessed by the member(s) of the hospice IDT who are providing services to that patient/family. By prescribing WHAT is to be assessed, rather than WHO is to do

	the assessing, the COPs will be much more in keeping with hospice care as it is actually provided. If CMS prescribes WHO must assess the patient/family, hospices will continually be out of compliance, because this requirement is impossible to meet and attempted compliance will alienate hospice patients/families and contribute to unnecessary revocation of hospice services.
(c) Standard: Content of the comprehensive assessment.	
(3) Factors that must be considered in developing individual care plan interventions, including- (i.) Bereavement: An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.	**(3) Factors that must be considered in developing individual care plan interventions, including-** **(i.) Bereavement: An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the ~~bereavement~~ plan of care.** *Rationale: A bereavement assessment must be started at the time of admission and becomes part of the overall hospice plan of care.*
(d) Update of the comprehensive assessment. (1) As frequently as the condition of the patient requires, but no less frequently than every 14 days.	**The Alliance recommends that updates to the comprehensive assessment be called "Ongoing Assessment(s)" to help differentiate between the comprehensive assessment and updates to the comprehensive assessment.** **(1) As frequently as the condition of the patient requires, ~~but no less frequently than every 14 days~~.**
	Rationale: If CMS requires that all 4 core disciplines (physician, RN, social worker and counselor) assess that patient every 14 days, patients and families will feel overwhelmed by the number of hospice staff who are contacting them. The Alliance believes

	that this will cause many patients and families to refuse further contact from social work or counseling services.
(e) Standard: Patient outcome measures.	**The Alliance believes that outcome measures such as the NHPCO Dataset, the NHPCO Family Evaluation of Hospice Care and the NHPCO End Result Outcome Measures are important to the hospice's QAPI program.**
418.76 Condition of participation: Home health aide and homemaker services.	
(h) Standard: Supervision of home health aides.	
i. ….A registered nurse or a qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days.	**i. ….A registered nurse or a qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care ~~no less frequently than every 28 days~~ at least annually.** The Alliance strongly opposes the 28 day timeframe for supervisory home health aide visits. This standard is extremely burdensome to hospices, both financially and as far as ensuring compliance. The standard does not ensure that care will improve and in fact, care might decline since the standard requires that scarce nursing resources must be deployed for a task that can be handled through the agency's QAPI program. Even the Alliance's smallest member hospices projected the need for an additional full time equivalent (FTE) to ensure compliance ~~with this standard. Either RN caseloads would have to be adjusted~~ downward, or an extra nurse would have to be hired to conduct supervisory visits. The cost to each hospice is estimated to be approximately $50,000 per RN, including salary and benefits.

	Hospice nurses are not able to schedule their visits with the certainty that home health nurses can schedule their visits. Patient deaths, pain crises, family crises, etc., can and should disrupt hospice nurses routine scheduled visits each day.
	The Community Health Accreditation Program (CHAP) requires that hospices evaluate home health aides annually, including on-site evaluation of competency testing. The Alliance strongly urges CMS to consider utilizing this CHAP standard for the COP standard.
418.100 Condition of participation: Organization and administration of services.	
(a) Standard: Serving the hospice patient and family. The hospice must ensure that-	
(2) That each patient experience hospice care that is consistent with patient and family needs and desires.	**(2) That each patient experience hospice care that is consistent with patient and family assessed needs ~~and desires~~.** *Rationale: Patient and family needs and desires are vast and if interpreted literally, this standard could require that a hospice meet every family request, such as flying in family members from out of town, etc. The hospice IDT must assess patient and family needs and create a plan of care that meets those needs but the hospice cannot ensure that every patient and family desire is met.*
418.102 Condition of participation: Medical Director ……. The medical director and physician designee coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy.	**……. The medical director and physician designee communicate ~~coordinate~~ with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice philosophy. ~~policy~~.** *Rationale: A Medical Director is responsible for overseeing the*

	medical care provided to hospice patients. The IDG is responsible for coordinating care. *Care should be consistent with the hospice philosophy, e.g., palliative, inclusive of the patient and family. Hospice "policy" is too prescriptive, and may not allow for each patient and family's unique needs.*
(c) Standard: Coordination of medical care. The medical director or physician designee, and other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.	**(c) Standard: Coordination of medical care.** **The medical director or physician designee, and other members of the interdisciplinary group are jointly responsible for the coordination of the patient's hospice care. ~~medical care in its entirety.~~ The medical director or physician designee is also responsible for participating in ~~directing~~ the hospice's quality assessment and performance improvement program.** *Rationale: Most hospice QAPI programs are directed by an RN experienced in QAPI and knowledgeable about the agency's operations. The hospice Medical Director is an essential member of the QAPI team, but he or she may or may not have expertise in QAPI. Each hospice should be allowed to appoint the most appropriate individual to direct its QAPI program, regardless of that individual's discipline.* *Also, "medical care" usually refers to physician services and "hospice care" is a broader term that better fits in this context.*
418.104 Condition of participation: Clinical records. (b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must the able to authenticate each handwritten and electronic signature of a primary author who has	**(b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must the able to authenticate each ~~handwritten and~~ electronic signature of a primary author who has reviewed and approved the entry.**

reviewed and approved the entry.	*Rationale: This standard seems more appropriate for a hospital. While hospitals are able to have lengthy credentialing processes for physicians, hospices must be able to respond quickly to referring physicians. Hospices have implemented expedited credentialing processes, such as verifying each physician's state license. Hospices are not able to easily authenticate each referring physician's handwritten signature, and requiring hospices to do so will delay hospice admissions and cause many last minute referrals to hospice to be denied hospice care entirely.* *Also, the manpower to collect the signatures from attending physicians and continuously monitor their authenticity would be significant and would be a tremendous financial burden for the hospice.*
(e) Standard: Discharge or transfer of care. (1) If the care of a patient is transferred to another Medicare/Medicaid-approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to the facility. (2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the clinical record and the hospice discharge summary of this section to the patients' attending physician.	**(e) Standard: Discharge or transfer of care.** **(1) If the care of a patient is transferred to another Medicare/Medicaid-approved facility, the hospice must forward a copy of the patient's ~~clinical record and the~~ hospice discharge summary to the facility.** *Rationale: A discharge summary would be sufficient to ensure coordination of care. The entire record could be made available to the facility receiving the patient if requested as is stated in current hospital regulations.*
	~~(2) If a patient revokes the election of hospice care, or is~~ discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of ~~the clinical record and~~ the hospice discharge summary of this section to the patients' attending physician upon request.

	Rationale: Many physicians already complain about the amount of paperwork they receive from hospices. Physicians who want to review the patient's hospice record can easily request a copy from the hospice.
418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment. Controlled drugs in the patient's home. The hospice must have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home.	**418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.** **(c) Controlled drugs in the patient's home. The hospice must have a written policy for ~~tracking, collecting, and~~ disposing of controlled drugs maintained in the patient's home.** *Rationale: Hospices do not control the home environment and cannot be responsible for tracking and collecting controlled drugs.* *The word "tracking" implies that hospice nurses will be responsible for conducting a physical inventory of each patient's controlled drugs at each visit, and calculating if the correct number of pills remain, according to their prescribed use. While hospice nurses do strive to monitor patient's usage of controlled drugs to ensure that the patient has good symptom control and that refills are ordered on a timely basis, hospice nurses do not have the time to conduct an physical inventory of the patient's pills at each visit and calculate if the correct number of pills are remaining.*
	Similarly, hospice nurses are not permitted to "collect" controlled drugs because the only person who is authorized to possess a controlled drug is the patient for whom the medication

	was prescribed.
418.108 Condition of participation: Short-term inpatient care. Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.	**418.108 Condition of participation: Short-term inpatient care. Inpatient care must be available for pain control, symptom management, ~~and~~ respite purposes and for crises of a psycho-social nature that make it infeasible for care to be provided in the patient's home, and must be provided in a participating Medicare or Medicaid facility.** *Rationale: Inpatient care is defined as short term and a short admission for a psychosocial crises is very appropriate in end-of-life care and can prevent patients from unnecessarily revoking hospice benefits and returning to (more costly) acute care.*
(a) Inpatient care for symptom management and pain control. (2) ---regarding 24 hour nursing services"	The Alliance strongly recommends keeping the requirement for 24 hour RN staffing for inpatient care, but removing it for respite care. *Rationale: Respite care is a more routine level of care and easily carried out by a licensed nurse. Inpatient care requires constant assessment that is most appropriately carried out by an RN.*
(c) Standard: Inpatient care provided under arrangements. If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies- (3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record and discharge summary is	**(c) Standard: Inpatient care provided under arrangements. If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies-** **(3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the ~~inpatient clinical record and~~**

available to the hospice at the time of discharge. (4) That the inpatient facility has identified an individual within the facility who is responsible of the implementation of the provisions of the agreement;	**discharge summary is available to the hospice at the time of discharge.** **(4) That the inpatient facility has identified a ~~individual~~ position within the facility who is responsible of the implementation of the provisions of the agreement;** *Rationale: The hospital discharge summary is sufficient for the hospice to ensure continuity of care. The hospice-facility contract should specify what position is responsible for implementing the provisions of the contract.*
(o) Seclusion and restraint (1) …*A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's medical or psychiatric condition.	**(o) Seclusion and restraint** …*A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard hospice treatment for a patient's medical or psychiatric condition. *Rationale: Although the intent of these guidelines is to prevent the use of medication or devices to unnecessarily restrain patients who should be managed through redirection or other non-restrictive methods, they can be construed to deter the use of medications when these interventions are necessary for the control of symptoms that cannot be managed through other methods or when patients are at risk of harming themselves or others. More desirable language would acknowledge the appropriate use of such medication in hospice patients to manage symptoms of life-limiting illnesses. Examples of appropriate use would be for pain management and terminal agitation.*
(3) (ii) (d) Each order for a physical restraint or seclusion must be in writing and limited to 4 hours for adults; 2 hours	(3) (ii) (d) Each order for a physical restraint or seclusion must be in writing and limited to 8 hours for adults while sleeping and 4

for children and adolescents ages 9 through 17; or 1 hour for patients under the age of 9.	hours while awake; 6 hours for children and adolescents ages 9 through 17 while sleeping and 2 hours while awake; or 2 hours for patients under the age of 9 while sleeping and 1 hour while awake.
(7) The hospice must report to the CMS regional office any death that occurs while the patient is restrained or in seclusion, within 24 hours after a patient has been removed from restraint or seclusion.	7) The hospice must report to the CMS regional office any unexpected death that occurs while the patient is restrained or in seclusion, or within 24 hours after a patient has been removed from restraint or seclusion. *Rationale: This would be a reasonable expectation, while defining and reporting every death while a patient is secluded or restrained might place more of a burden on the CMS office.*
418.112 Condition of participation: Hospices that provide care to residents of a SNF/NF, ICF/MR, or other facilities.	**The Alliance recommends that the effective date of this section be delayed until the SNF/NF requirements contain a parallel condition.**
(b) Professional management. The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to 418.100.	**(b) Professional management. The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to 418.100. The SNF/NF continues to provide services at the same level it would have provided if that resident had not elected the hospice benefit.**
(d) Medical Director. The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the	**(d) Medical Director.** ~~The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF or other facility.~~ The medical director and physician designee must communicate with ~~the medical director of the SNF/NF, the patient's attending physician, and~~ other physicians and healthcare professionals within a SNF/NF to ensure that each patient

terminal and related conditions to ensure quality care for the patient and family.	<u>experiences medical care that reflects the hospice philosophy.</u> ~~participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.~~
418.114 Personnel qualification for licensed personnel (a) General qualification requirements. Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) to practice by the State in which he or she performs such functions or actions, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.	The Alliance agrees with this section and specifically with the qualification of state licensure for hospice social workers.
(7) Social worker. A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education	The Alliance agrees with CMS that this qualification should only apply in states that do not license social workers.

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Hospice

Texas & New Mexico Hospice Organization

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July 21, 2005

Centers for Medicare and Medicaid Svcs.
Dept. of Health& Human Svcs.
ATTN: CRS 3844-P
PO Box 8010
Baltimore, MD 21244-8010

Attached are the original and two copies of the comments on the proposed Hospice Conditions of Participation submitted by the Texas & New Mexico Hospice Organization. The Texas & New Mexico Hospice Organization is the professional organization representing 154 hospices providing services in Texas and New Mexico.

Very truly yours,

Larry A. Farrow
Executive Director

Attach. (3)

COMMENTS ON
42 CFR Part 418
Medicare and Medicaid Programs:
Hospice Conditions of Participation;
Proposed Rule, dated May 27, 2005

NOTE: When recommendations are made to reword a portion of the proposed rule, items to be deleted will be lined through and new language will be underlined.

§ 418.3 Definitions

Attending Physician— We request that the definition be rewritten to clearly acknowledge that the hospice medical director and/or nurse practitioner may also act as the patient's attending physician as this is a common practice in many instances.

> ***Attending physician*** means a—
> (1) (i) Doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs that function or action; or
> (ii) Nurse practitioner who meets the training, education and experience requirements as the Secretary may prescribe; and
> (2) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.
> (3) A hospice medical director or a hospice nurse practitioner may fill this function if so designated by the individual.

Clinical Note— Since hospice also provides or assists in the provision of spiritual care, we recommend that it be added to this definition.

> ***Clinical note*** means a notation of a contact with the patient that is written and dated by any person providing services and that describes signs and symptoms, treatments and medications administered, including the patient's reaction and/or response, and any changes in physical, spiritual or emotional condition.

Comprehensive Assessment—A definition is needed that provides a clear understanding that this is an assessment conducted by a Registered Nurse that identifies for the IDG those immediate needs of the patient and family.

Counseling Services—A definition is needed for counseling services that will also include bereavement services.

> ***Counseling Services*** means services that assist the patient/family to minimize the

stress and problems that arise from the terminal illness or from the dying process. These services may also be continued as bereavement services for the family following the death of the patient.

Dietician-- It is recommended that the following definition be added to clarify the difference between nutritional counseling and those services that must be performed by a Dietician in the provision of dietary therapy.

Dietitian means a person who is registered by the Commission of Dietetics Registration or the American Dietetic Association.

Drug Restraint—Clarification is needed that recognizes that hospice utilizes medications in its normal patient care protocol that may be viewed in other settings as chemical restraints.

Drug restraint means a medication used to control behavior or to restrict the patient's freedom of movement, which is not a standard hospice treatment for a patient's medical or psychiatric condition.

Facility— To avoid confusion, it is recommended; that the following definition be added.

Facility means a place where the patient resides and hospice care is provided .

Licensed professional—Dietary Services are also provided and should be included in this definition.

Licensed professional means a licensed person sanctioned by the State in which services are delivered, furnishing services such as skilled nursing care, physical therapy, speech-language pathology, occupational therapy, dietary therapy, and medical social services.

Physical restraints—Some restraints, such as bedrails, are not attached to a patient's body.

Physical restraint means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

PATIENT'S RIGHTS

§ 418.52 Condition of Participation: Patient's Rights

§ 418.52 (a) (1)

The language as proposed should acknowledge the impossibility of providing written materials in all languages and dialects and clearly make it permissible to convey the information to the patient through an interpreter who could be a family member or other person

§ 418.52(a) (3)

Informing the patient of drug policies and procedures (especially disposal policies), at the time of admission will be confusing to the patient & primary caregivers. Patients and their caregivers are given a tremendous amount of information at the time of admission and it is impossible to retain all of the intricacies of hospice. It is recommended that it be made clear that these policies can be provided as a part of an admission packet.

§ 418.52(a) (4)

The phrase "demonstrated an understanding of these rights" is troubling in that the only way to truly ascertain understanding is by testing and that is inappropriate for hospice patients and/or family. As such it is recommended that the wording be changed to reflect that the patient/representative was presented the information for retention.

> The hospice must maintain documentation showing that it has complied with the requirements of this section and that the patient or representative has ~~demonstrated an understanding of~~ been given an explanation of these rights and given a copy for retention.

§ 418.52(b)(1)

A basic premise in hospice is that the patient has the right to direct their own care to a large extent. As such, there should be a provision under patient's rights that specifically states that the patient has the right to refuse treatment.

> (v) The patient has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive.

§ 418.52(e)

This standard is unclear in that it appears to go further than the Advance Beneficiary Notice and may include determining the patient's liability in the Medicaid Room &

Board payment to nursing facilities. Normally, hospices cannot access patient liability information in this area until after the patient has been brought into hospice.

ASSESSMENT TIME FRAMES

§ 418.54

The comprehensive assessment section, as written, will be particularly difficult for our member hospices, especially in regards to the time frames which are unrealistic in regards to the comprehensive assessment.

> **§ 418.54 Condition of participation: Comprehensive assessment of the patient.**
> The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for medical, nursing, psychosocial, emotional, and spiritual care. This ~~care~~ assessment includes, but is not limited to, the palliation and management of the terminal illness and related medical conditions.
>
> (a) *Standard: Initial assessment*. The hospice registered nurse must ~~make~~ complete an initial assessment visit within 24 hours after the hospice receives a physician's ~~admission order~~ certification for care (unless ordered otherwise by the physician or requested by the patient or family), to determine the patient's immediate care and support needs.
>
> (b) *Standard: Time frame for completion of the comprehensive assessment.* The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment of the physical, psychosocial, and spiritual needs of the patient/family within 7 calendar days ~~no later than 4 calendar days~~ after the patient elects the hospice benefit.

§ 418.54(c)(3)(i)

Bereavement counseling is a portion of the plan of care, but should not be a part of the initial or comprehensive assessment. The bereavement plan of care should be developed as needed. As such, we recommend the deletion of this entire section.

> ~~*(i.) Bereavement*. An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.~~

§ 418.54(d)

The continuing update of the assessment is an important portion of hospice care. However, as written, the 14 day requirement does not take into account holidays or unforeseen problems. As such we are recommending some minor changes.

(d) *Standard: Update of the comprehensive assessment.* The update of the comprehensive assessment must be accomplished by the hospice interdisciplinary group and must consider changes that have taken place since the initial assessment. It must include information on the patient's progress toward desired outcomes, as well as a reassessment of the patient's response to care. The assessment update must be accomplished—

(1) As frequently as the condition of the patient requires, but no less frequently than every 14 days, unless it is documented that the 14th day falls on a national holiday ; and

(2) At the time of each recertification. If the recertification falls within 5 days of a regular meeting of the hospice interdisciplinary group, then that assessment can be used for the recertification assessment.

PLAN OF CARE/COORDINATION OF SERVICES

§ 418.56

This section does not recognize that in some instances the hospice physician can also be the attending physician when the patient either does not have an attending physician or their attending physician does not want to continue in that capacity. It also adds the word "spiritual counselor" in the makeup of the IDG, when the law only uses "counselor". It also doesn't recognize the standard practice of utilizing an interdisciplinary administrative team to establish policies and oversee day-to-day provision of hospice care and services rather than designating one of the IDG teams.

(a) *Standard: Approach to service delivery.*

(1) The hospice must designate an interdisciplinary group or groups composed of individuals who work together to meet the physical, medical, social, emotional, and spiritual needs of the hospice patients and families facing terminal illness and bereavement. Interdisciplinary group members must provide the care and services offered by the hospice, and the group in its entirety must supervise the care and services. The hospice must designate a qualified health care professional that is a member of the interdisciplinary group to provide coordination of care and to ensure continuous assessment of each patient's and family's needs and implementation of the interdisciplinary plan of care. The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

(i) A doctor of medicine or osteopathy (who is not the patient's

attending physician, unless the hospice physician/medical director is also serving in that capacity).

(ii) A registered nurse.

(iii) A social worker.

(iv) A pastoral, clergy, or other ~~spiritual~~ counselor.

(2) If the hospice has more than one interdisciplinary group, it must designate in advance ~~only~~ one of those groups or an interdisciplinary administrative team to establish policies governing the day-to-day provision of hospice care and services.

§ 418.56(c)

This section needs clarification to show that the hospices' responsibility is for palliation and management of the terminal illness rather than the comprehensive care of all of the patient's problems. In addition, patient and family agreement with the plan of care is not always guaranteed.

c) *Standard: Content of the plan of care*. The hospice must develop a written plan of care for each patient that reflects prescribed interventions based on the problems identified in the initial comprehensive and updated comprehensive assessments, and other assessments. The plan of care must include services for the palliation and management of the terminal condition but not be limited to—

(1) Interventions to facilitate the management of pain and symptoms;
(2) A detailed statement of the scope and frequency of services necessary to meet the specific patient and family needs;
(3) Measurable targeted outcomes anticipated from implementing and coordinating the plan of care;
(4) Drugs and treatment necessary to meet the needs of the patient;
(5) Medical supplies and appliances necessary to meet the needs of the patient; and
(6) The interdisciplinary group's documentation of patient and family understanding~~,~~ and involvement~~, and agreement~~ with the plan of care, in accordance with the hospice's own policies, in the clinical record.

§ 418.56(d)

The medical director has a well defined role as a part of the hospice team and as such, should not be singled out in this portion. The inclusion of collaboration with the attending physician is a positive move.

(d) *Standard: Review of the plan of care*. The ~~medical director or physician designee, and the~~ hospice interdisciplinary team (in collaboration with the individual's attending physician to the extent possible) must review, revise and document the plan as necessary at intervals specified in the plan but no less than

every 14 calendar days. A revised plan of care must include information from the patient's ~~updated comprehensive~~ assessments and the patient's progress toward outcomes specified in the plan of care.

§ 418.62(b)

It is recommended that "hospice" be inserted to insure that this section is not misinterpreted.

(a) Licensed professionals must actively participate in the coordination of all aspects of the patient's hospice care, in accordance with current professional standards and practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to patient and family counseling and education; and

§ 418.64

Continuous care is particularly burdensome on small and rural hospices that are not staffed to be able to provide this infrequent and unpredictable level of care on the when it is needed. Without the ability to contract for continuous care staff on a routine basis, a barrier is created that may preclude a patient being able to easily access this level of care. We urge CMS to rethink their stand on this issue.

§ 418.64(b)(3)

There is a concern that the use of "infrequently" is so unspecific that its interpretation may lead to confusion. As such it is recommended that it be changed to:

(3) Highly specialized nursing services ~~that are provided so infrequently that the provision of~~ that if such services were provided by direct hospice employees would be impracticable and prohibitively expensive, may be provided under contract.

§ 418.64(d)(2)

The recognition that nursing standards of practice allow them to make general dietary assessments and provide dietary counseling is a very positive change.

§ 418.66

We urge CMS to streamline and simplify this process and also make it available for hospice in urban areas who cannot find sufficient nursing staff.

§ 418.72

We recommend that dieticians be added to non-core service providers in order to allow hospices to contract for their services.

§ 418.76(g)(2)(i)

The requirement that home health aide services be ordered by a physician or nurse practitioner needs to be changed so the IDG can order these services.

(2)A home health aide provides services that are:

(i) Ordered by the ~~physician or nurse practitioner~~ interdisciplinary team;

§ 418.76(h)

The standard that a nurse or qualified therapist make an onsite visit every 14 days to observe to assess a home health aide's services and every 28 days to observe the home health aide is one of the few proposed changes that hospice providers are unanimous in their opposition. We agree that contact with the family either by telephone or in person every 14 days and an annual observation and assessment of an home health aide are both needed. The requirements for every 14 day onsite visits and every 28 day observation are not needed, impractical and a waste of the resource of valuable nursing hours.

(h) *Standard: Supervision of home health aides.*

i. A registered nurse or qualified therapist must make an onsite visit or telephone call to the patient's home no less frequently than every 14 days to assess the home health aide's services. The home health aide does not have to be present during this ~~visit~~ contact. A registered nurse or qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than ~~every 28 days~~ once annually.

ORGANIZATION & ADMINISTRATION

§ 418.100(a)(2)

The requirement that a hospice "ensure" care that is "...consistent with patient and family needs and desires" may create expectations beyond that which is under the control of the hospice. Every hospice strives to ensure care that provides optimal comfort and dignity that is consistent with needs and desires, but that is not always possible, especially when the patient and family are not in agreement with the plan of care.

(a) *Standard: Serving the hospice patient and family.* The hospice must strive to ensure—

(1) That each patient receives and experiences hospice care that optimizes comfort and dignity; and

(2) That each patient experience hospice care that is consistent with

patient and family needs and desires that are consistent with hospice practices.

§ 418.100(e)

When a hospice contracts for services, it should be responsible to supervise the services rather than the staff providing those services.

(e) *Standard: Professional management responsibility.* A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management, and ~~supervision~~ oversight of ~~staff and services for~~ all arranged services, to ensure the provision of quality care. Arranged services must be supported by written agreements that require that all services be—

(1) Authorized by the hospice;
(2) Furnished in a safe and effective manner by qualified personnel ~~having at least the same qualifications as hospice employees~~; and
(3) Delivered in accordance with the patient's plan of care.

§ 418.100(f)

We support this provision so long as these standards are uniformly and consistently implemented across CMS regions.

MEDICAL DIRECTOR

§ 418.102

It needs to be noted that many hospices utilize the services of volunteer medical directors. In addition, it should be the hospice rather than the medical director who is responsible for designating the physician that takes the medical director's place when the medical director is not available. Finally, it is the responsibility of the whole hospice team to ensure that each patient experiences good hospice care.

§ 418.102 Condition of participation: Medical director.
The hospice must designate a physician to serve as medical director. The medical director must be a doctor of medicine or osteopathy who is either a volunteer with, employed by, or under contract with, the hospice. When the medical director is not available, a physician designated by the ~~medical director~~ hospice assumes the same responsibilities and obligations as the medical director. The medical director and physician designee along with other members of interdisciplinary group coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy.

§ 418.102(b)

The requirement that the medical director must review the patient's and family's expectations and wishes for the continuation of hospice seem to add another unnecessary step in the recertification process. The patient and family are notified during the initial certification that they have the option to opt out of hospice at any time. They willingly entered into hospice and remain there as a matter of choice.

> (b) *Standard: Recertification of the terminal illness.* Before the recertification period for each patient, as described in § 418.21(a), the medical director or physician designee must review:
>
> (1) The patient's clinical information~~; and~~
>
> ~~(2) The patient's and family's expectations and wishes for the continuation of hospice care.~~

§ 418.102(c)

The requirement that the medical director or physician designee be responsible for directing the hospice's quality assessment program is unworkable at best. The physician and the remainder of the team should have continual input into the program, but the hospice should be able to manage it own QAPI program.

> (b) *Standard: Coordination of medical care.* The medical director or physician designee, and the other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee shall participate and be aware of the hospice's quality assessment and performance improvement program and the hospice shall designate a medical professional who is ~~also~~ responsible for directing the hospice's quality assessment and performance improvement program.

CLINICAL RECORDS

§ 418.104(b)

This standard is too broad for hospices that work with a large undefined number of physicians and health care professionals and as written would require each hospice to set up a credentialing office. Unlike hospitals that have a defined physician base, hospices can potentially work with hundreds of physicians across various settings. One hospice in a small city reported that they would have to verify signatures on more than 350 physicians.

> (b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must be able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry. The author of each entry must be identified and must authenticate his or her entry. Authentication may include signatures, written initials or computer entry.

§ 418.104(d)

We recommend that this standard follow the HIPAA requirement for records retention.

§ 418.104(e)

We recommend that the release of information follow the Minimum Necessary Standards and limited to the discharge summary.

(e) *Standard: Discharge or transfer of care.*

(1) If the care of a patient is transferred to another Medicare/ Medicaid-approved facility, the hospice must forward a copy of ~~the patient's clinical record and~~ the hospice discharge summary to that facility.

(2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy ~~of the clinical record and~~ the hospice discharge summary of this section to the patient's attending physician.

(3) The hospice discharge summary must include—

(i) A summary of the patient's stay including treatments, symptoms and pain management;

(ii) The patient's current plan of care;

(iii)The patient's latest physician orders; and

(iv)Any other documentation that will assist in post-discharge continuity of care.

§ 418.106(b)

The language in this section referring to "potential dangers" merely reinforces the myths that hospices have been trying to over come for years. In addition, the hospice cannot collect and dispose of drugs unless that desired by the family.

(b) *Standard: Controlled drugs in the patient's home.* The hospice must have a written policy for ~~tracking, collecting, and~~ disposing of controlled drugs maintained in the patient's home. During the initial hospice assessment, the use and disposal of controlled substances must be discussed with the patient and family to ensure the patient and family are educated regarding the appropriate use of controlled substances. ~~regarding the uses and potential dangers of controlled substances.~~ The hospice nurse must document that the policy was discussed with the patient and family.

§ 418.106(c)

The maintenance and training in the use of durable medical equipment can be handled in

most case through contractual agreements.

(c) *Standard: Use and maintenance of equipment and supplies.*

(1) The hospice must follow directly or through contractual agreements manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment. The equipment must be safe and work as intended for use in the patient's environment. Where there is no manufacturer recommendation for a piece of equipment, the hospice must develop in writing its own repair and routine maintenance policy. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.

(2) The hospice must ensure directly or through contractual agreements that the patient, where appropriate, as well as the family and/or other caregiver(s), receive instruction in the safe use of durable medical equipment and supplies. The patient, family, and/or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice or contractual staff.

SHORT TERM INPATIENT CARE

§ 418.108

This standard should be expanded to include short term stays for crises of a family psychosocial nature. The requirement for 24 hour nursing care should not be applied for either respite or for care during a short-term family psychosocial crises.

§ 418.108 Condition of participation: Short-term inpatient care.
Inpatient care must be available for pain control, symptom management, short-term family psychosocial crises and respite purposes, and must be provided in a participating Medicare or Medicaid facility.

§ 418.108(b)

(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes and/or short-term family psychosocial crises must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) A Medicare/Medicaid approved nursing facility ~~that also meets the standards specified in § 418.110(b) and (f)~~.

§ 418.108(c)(3)

The hospital discharge summary would be sufficient for the hospice to ensure continuity of care.

(3) That the hospice patient's ~~inpatient clinical record includes a record of all~~

~~inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record and~~ discharge summary is available to the hospice at the time of discharge;

SECLUSION & RESTRAINT

§ 418.110(o)

This section needs to be amended to recognize that certain chemicals that may be considered in other disciplines as chemical restraints are commonly used in hospice for treatment of terminal restlessness. A few examples are: Haldol, ativan Xanax, ABH, any benzodiazepines, Phernagen, phenobarbitol, and thorazine. It should also acknowledge that bed rails are not considered a restraint when used for safety purposes. It is also recommended that it be clarified that orders for restraint cannot exceed 24 hours and that the patient should be reassessed every 4 hours rather than orders issued every 4 hours.

RESIDENTS RESIDING IN A FACILITY

§ 418.112(b)

The standard as written may negatively impact the hospice's relationship with the SNF since the nursing home COP's currently hold the nursing home responsible for the professional management of the patient. As such we suggest the following changes.

> (b) *Standard: Professional management.* The hospice ~~must assume full responsibility for~~ assumes professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to §418.100. The nursing facility continues to provide services at the same level (same level of services that they would have provided before the election of the hospice benefit.)

§ 418.112(c)

We are recommending that this section be rewritten for clarity and simplification

> (c) *Standard: Core services.* ~~A hospice must routinely provide all core services. These services include nursing services, medical social services, and counseling services. The hospice may contract for physician services as stated in § 418.64(a). A hospice may use contracted staff provided by another Medicare certified hospice to furnish core services, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances, as described in § 418.64.~~
> The hospice would be required to provide all necessary core services to its patients in the same manner that it would provide core services to a patient residing in a home in the community.

§ 418.112(d)

We are concerned that this standard will unnecessarily strain the relationship between the hospice and the NF as well impeding coordination/communication by limiting coordination to physicians.

> (d) *Standard: Medical director*. The medical director ~~and~~ ~~or~~ physician designee as well as other professional members of the hospice interdisciplinary team ~~of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF, or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.~~ designee coordinates with other physicians and healthcare professionals within a SNF/NF to insure that each patient experiences medical care that reflects hospice philosophy.

§ 418.112(e)

We feel that this section needs some modifications for clarity and simplicity. For example, a contract with a NF does not need the written consent of the patient or the family. This is a requirement for the hospice during intake.

> (e) *Standard: Written agreement.* The hospice and the facility must have a written agreement that specifies the provision of hospice services in the facility. The agreement must be signed by authorized representatives of the hospice and the facility before the provision of hospice services. The written agreement must include at least the following:
>
> ~~(1) The written consent of the patient or the patient's representative that hospice services are desired.~~
>
> ~~(2)~~ (1)The services ~~that~~ to be provided by the hospice ~~will furnish and that the facility will furnish~~.
>
> (2) The services to be provided by the facility.
>
> (3) The manner in which the facility and the hospice are to communicate with each other to ensure that the needs of the patient are addressed and met 24 hours a day.
>
> (4) A provision that the facility immediately notifies the hospice if—
>
> (i) A significant change in the patient's physical, mental, social, or emotional status occurs;
>
> (ii) Clinical ~~complications~~ symptoms appear that suggest a need to alter the plan of care;
>
> ~~(iii) A life threatening condition appears;~~
>
> ~~(iv)~~ (iii)A need to transfer the patient from the facility and the hospice makes arrangements for, and remains responsible for, any necessary continuous care or inpatient care necessary related to the terminal illness; or

~~(v)~~(iv) The patient dies.

(5) A provision stating that the hospice assumes responsibility for determining the appropriate course of care, including the determination to change the level of services provided.

~~(6) An agreement that it is the facility's primary responsibility to furnish room and board.~~

~~(7)~~ (6)A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient, nursing, counseling (including spiritual and dietary counseling), social work, bereavement counseling for immediate family members, provision of medical supplies and durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness, as well as all other hospice services that are necessary for the care of the resident's terminal illness.

~~(8)~~ (7)A provision that the hospice may use the facility's nursing personnel where permitted by law ~~and as specified by the facility~~ to assist in the administration of prescribed therapies included in the plan of care ~~only to the extent that the hospice would routinely utilize the services of a hospice resident's family in implementing the plan of care~~.

§ 418.112(f)

The wording of this section may objectionable to nursing facility staff as it requires them to update their plan of care with the family every 14 days rather than their normal time frame of 3 months. However, we will not comment on those aspects and merely suggest one change to (f)(4), since these COP's only govern hospices. It is assumed that nursing facility COP's will eventually address this area .

(f)(4) Any changes ~~in~~ impacting the hospice plan of care ~~must be discussed among all caregivers and~~ must be approved by the hospice before implementation.

§ 418.112(g)

We are recommending the inclusion of the Physician Certification of Terminal Illness and Recertification's.

(g) *Standard: Coordination of services.* The hospice must designate a member of its interdisciplinary group to coordinate the implementation of the plan of care with the representatives of the facility. The hospice must provide the facility with the following information:

(1) Hospice ~~Plan~~ of care.

(2) Patient or patient's representative hospice consent form and advance directives.

(3) Names and contact information for hospice personnel involved in hospice care of the patient.
(4) Instructions on how to access the hospice's 24-hour on-call system.
(5) Medication information specific to the patient
(6) Hospice ~~Physician~~ orders and the Physician Certification of Terminal Illness and all subsequent recertification's.

§ 418.112(i)

Many nursing facilities have contract with more than one hospice and could possibly have a number of hospices wanting to provide orientation in-services. As such, we recommend the following change.

> (i) *Standard: Orientation and training of staff.* Hospice staff must ~~orient~~ assure the orientation of facility staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

PERSONNEL QUALIFICATIONS

§ 418.114(c)(7)

We support this standard as written. Some hospices or other states may require social workers with MSW's, but both Texas and New Mexico allow BSW's to fill this capacity. If the standard was changed to require MSW's, it would create major problems for the 200+ hospices operating in these states both as to the retention of those individuals currently employed and the recruitment of qualified MSW's (especially in the predominately rural areas) in both states.

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July 22, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Att: CMS-3844-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: File Code CMS-3844-P

To Whom It May Concern:

Hospice of East Texas provides care to over 1500 patients and families annually, throughout thirteen (13) east Texas counties. I am submitting the attached comments on the proposed revisions of the conditions of participation for hospice providers.

Hospice of East Texas appreciates the time and effort that has been devoted to the proposed revisions and looks forward to the opportunity to review subsequent changes in a second comment period.

Thank you for your consideration of our thoughts and comments.

Sincerely,

Marjorie A. Ream
President/CEO

Attachments:
(3) copies of Hospice of East Texas comments

903/266-3400
800-777-9860
FAX 903/566-0291
4111 UNIVERSITY BLVD.
TYLER, TEXAS 75701

www.hospice-etex.com

CMS-3844-P

2005 Proposed COPs	Comments by Hospice of East Texas (HOET)
418.52 Condition of Participation: Patient's Rights	
(a) Standard: Notice of rights: (1) The hospice must provide the patient or representative with verbal and written notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care.	**The hospice must provide the patient or representative with <u>verbal</u> notice of the patient's rights and responsibilities in a language and manner that the patient understands during the initial evaluation visit in advance of furnishing care. The hospice must provide the patient or representative with <u>written</u> notice of the patient's rights and responsibilities in the predominant language(s) of the hospice's service area during the initial evaluation visit in advance of furnishing care.** *Rationale: In some communities, there are hundreds of dialects and it will be extremely costly and expensive to translate these documents into all languages & dialects. This requirement will become a significant barrier to accessing hospice for these patients. Verbal translation occurs now and works well and does not deny patients access to hospice care.*
(3) The hospice must inform the patient and family of the hospice's drug policies and procedures, including the policies and procedures regarding the tracking and disposing of controlled substances.	**<u>Delete requirement related to informing patient and family of hospice's drug policies and procedures upon admission.</u>** *Rationale: We believe that patients and families may be overwhelmed at the time of admission and this information should be presented to the patient and family by the appropriate member of the IDT after, not during, admission.*
(b) Standard: Exercise of rights and respect for property and person.	**HOET recommends that CMS consider using the patient rights requirements as defined in the Home Health COPs at**

	484.10 for the hospice COPs, which we believe are more appropriate to the hospice/home environment.
(4) The hospice must- (i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at least 5 working days of the incident, and immediately to the hospice administrator.	**(4) The hospice must-** **(i.) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property are reported to State and local bodies having jurisdiction (including to the State survey and certification agency) within at most 5 working days of the incident, and immediately to the hospice administrator.** *Rationale: We believe that "at most 5 working days" is less confusing.*
(e) Standard: Patient liability. Before care is initiated, the patient must be informed, verbally and in writing, and in a language that he or she can understand, of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.	**Before care is initiated, the patient must be informed, ~~verbally and in writing, and in a language that he or she can understand,~~ of the extent to which payment may be expected from the patient, Medicare or Medicaid, third-party payers, or other resources of funding known to the hospice.** *Rationale: In some communities, there are hundreds of dialects and it will be extremely costly and expensive to translate these documents into all languages & dialects. This requirement will become a significant barrier to accessing hospice for these patients. Verbal translation occurs now and works well and does not deny patients access to hospice care.*
418.54 Condition of Participation: Comprehensive assessment of the patient.	
(a) Initial assessment: The hospice registered nurse must make an initial assessment visit within 24 hours after the	**The hospice registered nurse must make an initial assessment visit within 48 hours after the hospice receives a physician's**

<table>
<tr><td>hospice receives a physician's admission order for care (unless ordered otherwise by the physician), to determine the patient's immediate care and support needs.</td><td>admission order for care (unless ordered otherwise by the physician <u>or requested otherwise by the patient and/or family</u>), to determine the patient's immediate care and support needs.

Rationale: We believe that while most hospices make the initial assessment visit within 24 hours, this standard is too prescriptive and will result in deficiencies when the hospice occasionally is unable to make the initial assessment visit within 24 hours.</td></tr>
<tr><td>(b) The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than 4 calendar days after the patient elects the hospice benefit.</td><td>The hospice interdisciplinary group in consultation with the individual's attending physician must complete the comprehensive assessment no later than <u>7 calendar days</u> after the patient elects the hospice benefit.

Rationale: We believe that many patients and families will object to having 4 different people contact them within 4 days of initiating hospice care to complete the comprehensive assessment. We have a 7 day standard in Texas now and we often receive comments from families that it is, "raining hospice people".

<u>HOET recommends that CMS not prescribe WHO must complete the comprehensive assessment, but instead prescribe WHAT must be assessed, namely the patient/family's physical, emotional, social and spiritual needs.</u>

Rationale: Many patients and families refuse hospice services from a social worker and chaplain/counselor, and emotional, social and spiritual needs are assessed by the member(s) of the hospice IDT who are providing services to that patient/family. By prescribing WHAT is to be assessed, rather than WHO is to do</td></tr>
</table>

	the assessing, the COPs will be much more in keeping with hospice care as it is actually provided. If CMS prescribes WHO must assess the patient/family, hospices will continually be out of compliance, because this requirement is impossible to meet and attempted compliance will alienate hospice patients/families and contribute to unnecessary revocation of hospice services.
(c) Standard: Content of the comprehensive assessment.	
(3) Factors that must be considered in developing individual care plan interventions, including- (i.) Bereavement: An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the bereavement plan of care.	**(3) Factors that must be considered in developing individual care plan interventions, including-** **(i.) Bereavement: An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the ~~bereavement~~ plan of care.** *Rationale: A bereavement assessment must be started at the time of admission and becomes part of the overall hospice plan of care.*
(d) Update of the comprehensive assessment. (1) As frequently as the condition of the patient requires, but no less frequently than every 14 days.	**HOET recommends that updates to the comprehensive assessment be called "Ongoing Assessment(s)" to help differentiate between the comprehensive assessment and updates to the comprehensive assessment.** **(1) As frequently as the condition of the patient requires, ~~but no less frequently than every 14 days~~.**
	Rationale: If CMS requires that all 4 core disciplines (physician, RN, social worker and counselor) assess that patient every 14 days, patients and families will feel overwhelmed by the number of hospice staff who are contacting them. The Alliance believes

	that this will cause many patients and families to refuse further contact from social work or counseling services.
(e) Standard: Patient outcome measures.	**HOET believes that outcome measures such as the NHPCO Dataset, the NHPCO Family Evaluation of Hospice Care and the NHPCO End Result Outcome Measures are important to the hospice's QAPI program.**
418.76 Condition of participation: Home health aide and homemaker services.	
(h) Standard: Supervision of home health aides.	
i. ….A registered nurse or a qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care no less frequently than every 28 days.	**i. ….A registered nurse or a qualified therapist must make an onsite visit to the location where the patient is receiving care in order to observe and assess each aide while he or she is performing care ~~no less frequently than every 28 days~~ <u>at least annually.</u>** HOET strongly opposes the 28 day timeframe for supervisory home health aide visits. This standard is extremely burdensome to hospices, both financially and as far as ensuring compliance. The standard does not ensure that care will improve and in fact, care might decline since the standard requires that scarce nursing resources must be deployed for a task that can be handled through the agency's QAPI program. Hospice of East Texas projects that at least two(2) additional full time equivalent (FTE) RNs would be required to ensure compliance with this standard. Extra nurses would have to be hired to conduct supervisory visits. The cost is estimated to be approximately $50,000 per RN, including salary and benefits. Hospice nurses are not able to schedule their visits with the

	certainty that home health nurses can schedule their visits. Patient deaths, pain crises, family crises, etc., can and should disrupt hospice nurses routine scheduled visits each day. The Community Health Accreditation Program (CHAP) requires that hospices evaluate home health aides annually, including on-site evaluation of competency testing. HOET strongly urges CMS to consider utilizing this CHAP standard for the COP standard.
418.100 Condition of participation: Organization and administration of services.	
(a) Standard: Serving the hospice patient and family. The hospice must ensure that-	
(2) That each patient experience hospice care that is consistent with patient and family needs and desires.	**(2) That each patient experience hospice care that is consistent with patient and family assessed needs ~~and desires~~.** *Rationale: Patient and family needs and desires are vast and if interpreted literally, this standard could require that a hospice meet every family request, such as flying in family members from out of town, etc. The hospice IDT must assess patient and family needs and create a plan of care that meets those needs but the hospice cannot ensure that every patient and family desire is met.*
418.102 Condition of participation: Medical Director ……. The medical director and physician designee coordinate with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice policy.	**……. The medical director and physician designee communicate ~~coordinate~~ with other physicians and health care professionals to ensure that each patient experiences medical care that reflects hospice philosophy. ~~policy~~.** *Rationale: A Medical Director is responsible for overseeing the medical care provided to hospice patients. The IDG is responsible for coordinating care.*

	Care should be consistent with the hospice philosophy, e.g., palliative, inclusive of the patient and family. Hospice "policy" is too prescriptive, and may not allow for each patient and family's unique needs.
(c) Standard: Coordination of medical care. The medical director or physician designee, and other members of the interdisciplinary group are jointly responsible for the coordination of the patient's medical care in its entirety. The medical director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.	**(c) Standard: Coordination of medical care.** **The medical director or physician designee, and other members of the interdisciplinary group are jointly responsible for the coordination of the patient's hospice care. medical care in its entirety. The medical director or physician designee is also responsible for participating in directing the hospice's quality assessment and performance improvement program.** *Rationale: Most hospice QAPI programs are directed by an RN experienced in QAPI and knowledgeable about the agency's operations. The HOET Medical Director is an essential member of the QAPI team, but he or she may or may not have expertise in QAPI. Each hospice should be allowed to appoint the most appropriate individual to direct its QAPI program, regardless of that individual's discipline.* *Also, "medical care" usually refers to physician services and "hospice care" is a broader term that better fits in this context.*
418.104 Condition of participation: Clinical records. (b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must the able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.	**(b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated and dated. All entries must be signed, and the hospice must the able to authenticate each handwritten and electronic signature of a primary author who has reviewed and approved the entry.** *Rationale: This standard seems more appropriate for a hospital.*

	While hospitals are able to have lengthy credentialing processes for physicians, hospices must be able to respond quickly to referring physicians. Hospices have implemented expedited credentialing processes, such as verifying each physician's state license. Hospices are not able to easily authenticate each referring physician's handwritten signature, and requiring hospices to do so will delay hospice admissions and cause many last minute referrals to hospice to be denied hospice care entirely. *Also, the manpower to collect the signatures from attending physicians and continuously monitor their authenticity would be significant and would be a tremendous financial burden for the hospice.*
(e) Standard: Discharge or transfer of care. (1) If the care of a patient is transferred to another Medicare/Medicaid-approved facility, the hospice must forward a copy of the patient's clinical record and the hospice discharge summary to the facility. (2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of the clinical record and the hospice discharge summary of this section to the patients' attending physician.	**(e) Standard: Discharge or transfer of care.** **(1) If the care of a patient is transferred to another Medicare/Medicaid-approved facility, the hospice must forward a copy of the patient's ~~clinical record and the~~ hospice discharge summary to the facility.** *Rationale: A discharge summary would be sufficient to ensure coordination of care. The entire record could be made available to the facility receiving the patient if requested as is stated in current hospital regulations.* **(2) If a patient revokes the election of hospice care, or is discharged from hospice because eligibility criteria are no longer met, the hospice must provide a copy of ~~the clinical record and~~ the hospice discharge summary of this section to the patients' attending physician upon request.** *Rationale: Many physicians already complain about the volume*

	of paper they receive from hospices. Physicians who want to review the patient's hospice record can easily request a copy from the hospice.
418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment. Controlled drugs in the patient's home. The hospice must have a written policy for tracking, collecting, and disposing of controlled drugs maintained in the patient's home.	**418.106 Condition of participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment.** **(c) Controlled drugs in the patient's home. The hospice must have a written policy for ~~tracking, collecting, and~~ disposing of controlled drugs maintained in the patient's home.** *Rationale: Hospices do not control the home environment and cannot be responsible for tracking and collecting controlled drugs.* *The word "tracking" implies that hospice nurses will be responsible for conducting a physical inventory of each patient's controlled drugs at each visit, and calculating if the correct number of pills remain, according to their prescribed use. While HOET nurses do strive to monitor patient's usage of controlled drugs to ensure that the patient has good symptom control and that refills are ordered on a timely basis, hospice nurses do not have the time to conduct an physical inventory of the patient's pills at each visit and calculate if the correct number of pills are remaining.*
	Similarly, hospice nurses are not permitted to "collect" controlled drugs because the only person who is authorized to possess a controlled drug is the patient for whom the medication was prescribed.

418.108 Condition of participation: Short-term inpatient care. Inpatient care must be available for pain control, symptom management, and respite purposes, and must be provided in a participating Medicare or Medicaid facility.	**418.108 Condition of participation: Short-term inpatient care. Inpatient care must be available for pain control, symptom management, ~~and~~ respite purposes and for crises of a psycho-social nature that make it infeasible for care to be provided in the patient's home, and must be provided in a participating Medicare or Medicaid facility.** *Rationale: Inpatient care is defined as short term and a short admission for a psychosocial crises is very appropriate in end-of-life care and can prevent patients from unnecessarily revoking hospice benefits and returning to (more costly) acute care.*
(a) Inpatient care for symptom management and pain control. (2) ---regarding 24 hour nursing services"	HOET strongly recommends keeping the requirement for 24 hour RN staffing for inpatient care, but removing it for respite care. *Rationale: Respite care is a more routine level of care and easily carried out by a licensed nurse. Inpatient care requires constant assessment that is most appropriately carried out by an RN.*
(c) Standard: Inpatient care provided under arrangements. If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies- (3) That the hospice patient's inpatient clinical record includes a record of all inpatient services furnished, events regarding care that occurred at the facility, and that a copy of the inpatient clinical record and discharge summary is available to the hospice at the time of discharge. (4) That the inpatient facility has identified an individual within the facility who is responsible of the	**(c) Standard: Inpatient care provided under arrangements. If the hospice has an arrangement with a facility to provide for short-term inpatient care, the arrangement is described in a legally binding written agreement that at a minimum specifies- (3) That the hospice patient's inpatient clinical record includes ~~a record of all inpatient services furnished,~~ events regarding care that occurred at the facility, and that a copy of the ~~inpatient clinical record and~~ discharge summary is available to the hospice at the time of discharge. (4) That the inpatient facility has identified a**

implementation of the provisions of the agreement;	~~individual~~ <u>position</u> **within the facility who is responsible of the implementation of the provisions of the agreement;** *Rationale: The hospital discharge summary is sufficient for the hospice to ensure continuity of care. The hospice-facility contract should specify what position is responsible for implementing the provisions of the contract.*
(o) Seclusion and restraint (1) …*A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a patient's medical or psychiatric condition.	**(o) Seclusion and restraint** …*A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard <u>hospice</u> treatment for a patient's medical or psychiatric condition. *Rationale: Although the intent of these guidelines is to prevent the use of medication or devices to unnecessarily restrain patients who should be managed through redirection or other non-restrictive methods, they can be construed to deter the use of medications when these interventions are necessary for the control of symptoms that cannot be managed through other methods or when patients are at risk of harming themselves or others. More desirable language would acknowledge the appropriate use of such medication in hospice patients to manage symptoms of life-limiting illnesses. Examples of appropriate use would be for <u>pain management</u> ~~and terminal agitation.~~*
~~(3) (ii) (d) Each order for a physical restraint~~ or seclusion must be in writing and limited to 4 hours for adults; 2 hours for children and adolescents ages 9 through 17; or 1 hour for patients under the age of 9.	(3) (ii) (d) Each order for a physical restraint or seclusion must be in writing and limited to <u>8</u> hours for adults <u>while sleeping and 4 hours while awake</u>; <u>6</u> hours for children and adolescents ages 9 through 17 <u>while sleeping and 2 hours while awake</u>; or <u>2</u> hours for patients under the age of 9 <u>while sleeping and 1 hour while</u>

	awake.
(7) The hospice must report to the CMS regional office any death that occurs while the patient is restrained or in seclusion, within 24 hours after a patient has been removed from restraint or seclusion.	7) The hospice must report to the CMS regional office any unexpected death that occurs while the patient is restrained or in seclusion, or within 24 hours after a patient has been removed from restraint or seclusion. *Rationale: This would be a reasonable expectation, while defining and reporting every death during which a patient is secluded or restrained might place more of a burden on the CMS office.*
418.112 Condition of participation: Hospices that provide care to residents of a SNF/NF, ICF/MR, or other facilities.	**The HOET recommends that the effective date of this section be delayed until the SNF/NF requirements contain a parallel condition.**
(b) Professional management. The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to 418.100.	**(b) Professional management. The hospice must assume full responsibility for professional management of the resident's hospice care, in accordance with the hospice conditions of participation and make any arrangements necessary for inpatient care in a participating Medicare/Medicaid facility according to 418.100. The SNF/NF continues to provide services at the same level it would have provided if that resident had not elected the hospice benefit.**
(d) Medical Director. The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF or other facility. The medical director and physician designee must communicate with the medical director of the SNF/NF, the patient's attending physician, and other physicians participating in the provision of care for the terminal and related conditions to ensure quality care for the patient and family.	**(d) Medical Director.** ~~The medical director and physician designee of the hospice must provide overall coordination of the medical care of the hospice resident that resides in an SNF, NF or other facility.~~ The medical director and physician designee must communicate with ~~the medical director of the SNF/NF, the patient's attending physician, and~~ other physicians and healthcare professionals within a SNF/NF to ensure that each patient experiences medical care that reflects the hospice philosophy. ~~participating in the provision of care for the terminal and related~~

	~~conditions to ensure quality care for the patient and family.~~
418.114 Personnel qualification for licensed personnel (a) General qualification requirements. Except as specified in paragraph (c) of this section, all professionals who furnish services directly, under an individual contract, or under arrangements with a hospice, must be legally authorized (licensed, certified or registered) to practice by the State in which he or she performs such functions or actions, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.	HOET agrees with this section and specifically with the qualification of state licensure for hospice social workers.
(7) Social worker. A person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education	HOET agrees with CMS that this qualification should only apply in states that do not license social workers.

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Rec'd 7/25/05 L.N.W.

Indiana Hospice & Palliative Care ORGANIZATION, INC.

July 22, 2005

CMS
Room 445-G Hubert H. Humphrey Bldg.
200 Independence Avenue SW
Washington, DC 20201

Dear CMS:

Re: CCMS-2844-P-Medicaid and Medicaid Programs: Hospice Conditions of Participation Comments

The Board and members of the Indiana Hospice & Palliative Care Organization appreciate the efforts of CMS in revising the purposed conditions of participation that hospice must meet in order to participate in the Medicare and Medicaid programs. We would like to offer the following comments for your consideration as you finalize the conditions and prepare the interpretative guidelines.

<u>418.3 Definitions</u>

1. Attending physician
    a. Include in this definition that the hospice medical director or nurse practitioner may also act as the patient's attending physician. The definition should read as follows: "*the hospice medical director or nurse practitioner may also act as the patient's attending physician*" based upon 1812(d)(2)(A) Except as provided in subparagraphs (B) and (C) and except in the exceptional and unusual circumstances as the Secretary may provide, if an individual makes such an election from a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made under this title except...physicians' services furnished by the individual's attending physician (if not an employee of the hospice program) "The regulations should somewhere note that this is a permissive section relating to the patient so that the attending physician's input is required if (1) the patient has one, and (2) the MD is willing to participate. See also section 418.54(b) below.
2. Bereavement Counseling
    a. Who can perform counseling? Should that be defined? Or should it be left to the state?
3. Clinical note
    a. We request that the word "*spiritual*" is added to "any changes in physical or emotional condition" at the end of this definition.
4. Counseling Services
    a. We request that a definition of Counseling services be: *Counseling services means services that assist the patient/family to minimize the stress and problems that arise from the terminal illness or from the dying process.*
5. Comprehensive Assessment
    a. Include a definition of comprehensive assessment in this section.

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6. Covering Physician
    a. Add the following definition for "covering physician": *Covering physician means a physician acting on behalf of the attending physician.*
7. Dietitian
    a. Define dietitian as: *a person who is registered by the Commission of Dietetics Registration or the American Dietetic Association.*
8. Drug Restraint
    a. Clarification is needed. Some medications that may be viewed as a chemical restraint in some instances may be normal patient care protocol in hospice.
9. Employee
    a. Use the word "*staff*" in place of "employee" consistently throughout the document.
10. Facility
    a. The following definition should be included for the term "facility": *Facility means a place where the patient resides where care is provided for the patient.*
11. Family
    a. Please use the following definition: *Family means the person(s) identified as having a significant role in the patient's life.*
12. Hospice Patient
13. Licensed professional
    a. Include dietary therapy in this definition.
14. Nursing services
    a. Please add that *nursing service are provided by a licensed nurse* and further clarification in the preamble to clarify that nursing services are at times delegated to a home health aide.
15. Homemaker
    a. Please include clarification of the role and qualifications of the homemaker.
16. Patient's residence
    a. Please use the following definition: *Patient's residence means a house, apartment, SNF/NF, ICF/MR, assisted living facility, shelter, foster home or any other location where the patient lives.*
17. Physical Restraint
    a. Please add the phrase "or adjacent" as follows: "*or equipment attached or adjacent to the patient's body*".
18. Representative
    a. Please add after "…courts of the state" the words "*or common law within the State*" in order to take care of situations that are permitted but not statutory. See this from NF Rules: (4) in the case of a resident who has not been adjudged incompetent by the State court, any legal surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by state law.

<u>418.52 Condition of Participation: Patient's Rights</u>

1. (a) Standard: Notice of rights
    a. Please remove "during the initial evaluation visit" and make reflective of the home health regulation
    b. In some parts of the state there are many dialects and it would be impossible to provide written rights in the patient's language. Please change to relate that the patient understands their rights via an interpreter, a family member or other who understand the rights.
    c. We request that the right for the patient to be involved in their plan of care be added.
    d. We believe that informing the patient of drug policies and procedures at the time of admission will be confusing to the patient & primary caregivers, especially disposal policies. Patients and their caregivers are given a tremendous amount of information at the time of admission and it is impossible to retain all of the intricacies of hospice. We request that the discussion on drug disposal policies with patients and families be a part of the admission packet. Please clarify who tracks, how they track, what exactly needs to be tracked and what would the surveyor be looking for? We suggest

that tracking and disposal of drug policies are demonstrated during the 4 calendars day period.

2. (b) Standard: Exercise of rights and respect for property and person
   a. Please include wording that a patient has the right to refuse treatment: *The patient has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive.*
   b. Add " *and practice*" at the end of the sentence (3).
   c. We request that the right to keep the patient's attending physician be added.
   d. We request that the patient maintains the right to be involved in their plan of care.
   e. We suggest that the CMS language from the Home Health Conditions of Participation may be more appropriate. HHA COP Requirement 484.10 may be more appropriate to the hospice/home environment:
      i. *The Hospice must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the behalf of the hospice, and must document both the existence of the complaint and the resolution of the complaint.*
      ii. *We request that a change be made to the complain policy, which includes the following: an overall review of the complain policy and its applicability to hospice; and a change to (1) five days from the discover of the incident.*
3. (c) Standard: Pain Management and symptom control
   a. We disagree with the way it is written in respect to SNF patients. Hospice has no knowledge of what amount of liability each dually might have.
4. (e) Standard: Patient Liability
   a. Instead of "before care is initiated" use "*at the time of initial assessment*"; do not want to have to use dollar amount; needs to be more general (spend down, co-pay, etc.)
   b. How does this relate to the Advance Beneficiary Notice requirements? The ABN requirement applies whenever the patient wants something the hospice doesn't think is covered but is willing to pay for it (e.g. Deluxe DME, or HH Aide beyond the POC). The ABN is given to the patient so that (1) CMS know the beneficiary is protected, and (2) it can determine if the service should have been covered.
   c. We request that the responsibility for collecting the patient's liability in the Medicaid Room and Board payments remain with the nursing home and that the standard be specific about this requirement.

<u>418.54 Condition of Participation: Comprehensive Assessment of Patient</u>

a. The words "includes, but is not limited to," may be too broad and needs to be modified.
b. Change "care" to "*assessment*" in the last sentence so we can include items not related to the terminal illness that we would still want to assess.

1. (a) Standard: Initial Assessment
   a. Certification of the terminal illness itself is not particularly time-consuming, requiring only a signature on a pre-formatted document. Defense of unclear cases, however, requires generation of individual summary documents, themselves a product of chart review.
   b. Replace the word "make" with the word "*complete*".
   c. Clarify the appropriate language for the "physician's admission order for care".
   d. Instead of "physician's order for care", it should read "*physician's certification for care*".
   e. Add language "24 hours upon request by patient or representative". Strong feeling that an RN needs to perform the initial or admission assessment. If a social worker goes to sign up the patient and all the paperwork is signed and the patient dies prior to the nurse arriving to do the initial assessment, will the hospice be reimbursed? Concern that the RN and the initial assessment might be used to indicate total admission and therefore reimbursement.

f. Our guidelines for initial contact or pre-assessment are within 24 hours, however, our guidelines for complete initial assessments are 72 hours.
g. There is a difference between a hospice referral or evaluation- and an order to "admit to hospice." Any care team member can explain hospice and do an initial evaluation. The information is then taken back to the team for consensus. Some patient's/caregivers don't want the initial visit within 24 hours. Also some patients want to think about hospice or talk with family before they decide to be admitted. The initial assessment is completed at a mutually agreed upon date.
h. Replace "registered nurse" with a *licensed professional.*
i. We propose language for a (c) comprehensive assessment that includes, at a minimum, an in person assessment by the nurse and social worker within the first 7 days of care. These documents, as well as any other generated by other IDT members would form the Comprehensive Assessment. We would not be expected to complete the full assessment and data element collection of patients that did not live this long.
j. Please add "*as otherwise order by physician or requested by family*" after order for care.

2. (b) Standard: Time frame for completion of the comprehensive assessment
   a. Comprehensive assessment should be 7 days
3. (c) Standard: Content of the comprehensive assessment
   a. The content of the comprehensive assessment is focused on needs- this would be the prelude to the plan of care.
   b. Bereavement
      1. The statute (SEC, 1862, (42 U.A.C. 1395y ((a)) says: "Notwithstanding any to other provision of this title, no payment may be made under Part A or Part B for any expenses incurred or items or services____
         (1)
         (A)
         (B)
         (C) in the case of the hospice care, which are not reasonable and necessary for the palliation or management of terminal illness"
         This statute limits coverage. This language is OK for the assessment but not for a terminal plan. NHPCO should comment that this should be clear in the regulation- comprehensive assessment but duty for care plans limited to management and palliation.
   c. Please make exclusion for chaplain assessments.
   d. Remove ineffective drug therapy; beyond an RN's scope of practice.
   e. We request that the comprehensive assessment and care planning be limited to the care needed for the management and palliation of the terminal illness.
4. (d) Standard: Update of the comprehensive assessment
   a. Please specify; is this to mean your IDT meetings?
   b. We disagree that an IDT every 14 days on each patient should be required.
   c. The benefit periods (90/90/endless 60s) are divisible by 15 and the regulation should allow an assessment update with, say 5 days, to count for recertification by the hospice so that the disjunction between the 14 day periods wouldn't have a negative impact for a hospice. For example, if the rules were followed to the letter, the hospice would be doing a reassessment on day 99 (to meet the 14 requirement) and again on day 90 (to meet the 14 day requirement.)
   d. We request that the update closest to the recertification timeframe be acceptable as an update at the time of recertification.
5. (e) Standard: Patient Outcome
   a. It can be time consuming and costly but is important regarding safety issues and overall process improvement.
   b. This doesn't belong in the assessment portion. It could affect care planning at times depending on the data collected. Looking at data outcomes and evidence based

practice items are important in doing PI. It can be difficult to find hospice appropriate indicators.

c. Would you have to track quality improvement differently when the patient is in-home versus in-patient?

418.56 Condition of Participation: Interdisciplinary group care planning and coordination of services

1. (a) Standard: Approach to Service Delivery
   a. The change in (iv) has to do with moving spiritual care out of the volunteer section of the COPs.
   b. One IDT does not establish governing policies of the day-to-day care. An administrative team that is generally interdisciplinary establishes policies and oversees day-to-day provision of hospice care and services.
   c. This needs to be an RN.
   d. What is meant by this section of the standard?
   e. Why was this IDG team role narrowed from the original COPs? Should say "(iv) a counselor, including pastoral, clergy, spiritual, or other counselor." The language in the law is:
      1. "B) has an interdisciplinary group of personnel which-
         (i.) includes at least-
            (I) one physician (as defined in subsection (r)(I), (II) one registered professional nurse, and (III) one social worker,
            Employed by or, in the case of a physician described in sub clause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,"
2. (c) Standard: Content of the plan of care
   a. After "include," the regulation should read "*services for the palliation or management of the terminal condition, including...*" so that it is clear that the hospice doesn't need to treat all the patient's problems.
   b. Remove "detailed statement".
   c. Remove the word "agreement" out of this sentence. The family may not be in agreement with the plan of care, but the patient may be in agreement.
3. (d) Standard: Review of the plan of care
   a. 14 days is acceptable; define what they expect as collaboration by attending physician; and what proof would a surveyor want to see demonstrating this.
   b. The interdisciplinary team (in collaboration with the individual's attending physician to the extent possible)...
   c. Review of patient status and plans of care every 14 days requires assembly of chart materials on all the patients and takes about 2 hours a week per patient for that function alone every 2 weeks.
4. (e) Standard: Coordination of services
   a. (4) Should allude to sharing of information with non-hospice providers who are sharing the care (e.g., an ERSD dialysis facility for a cancer patient who gets dialysis for kidney failure).
   b. (4) Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in the home, in outpatient settings, and in inpatient settings, irrespective of whether the care and services are provided directly or indirectly under arrangement.
   c. We request adding some wording such as: "*Sharing of information may be accomplished through paper documents or electronic media, or telephonic or in person meetings, or some combination of these methods.*"
   d. The model proposed describes regularly occurring conversations among the Hospice Medical Director and referring physicians as well as Medical Directors of ECF's. A full-time director has enough control of his/her schedule to accommodate this task, but the part-timers have a great deal more difficulty. Favor stipulating the

coordination of care as an IDG-level function with contribution from the Medical Director when circumstances require.

418.58 Condition of Participation: Quality assessment and performance improvement

a. Management of the QA/PI program requires development and maintenance of procedures, regular attention to quality indicators for the purposes of identifying initiatives, conduct of meetings and the like.
b. Where QA/PI and coordination of care are concerned, the language could be changed to reflect what probably happens most of the time, which is that the Medical Director *oversees* these functions at regular intervals (usually quarterly) but intervenes directly only when more customary interactions are not productive.
c. Nurses traditionally perform this QA/PI function in hospitals with fairly remote physician oversight.

1. (a) Standard: Program scope
   a. The hospice industry is in the development stage of identifying and measuring data for improvement. It would be our hope that CMS would recognize and ensure leniency in this industry.
   b. There is some confusion throughout the document as to the language regarding data elements. We would like language used throughout the document that is consistent with Quality Assessment and Performance Improvement Programs.
   c. Examples of adverse patient events: Adverse programmed incorrectly; medication errors and fall in inpatient facility.
2. (c) Standard: Program activities
   a. What is meant by adverse events?

418.62 Condition of Participation: Licensed professional services

a. (b) Add the word "*hospice*" after "patient's".

418.64 Condition of Participation: Core services

1. (b) Standard: Nursing Services
   a. There is not a clear definition of what is included in nursing services- RN, LPN, and LVN? Please provide a clear definition in the definition section of nursing services?
2. (d) Standard: Counseling services
   a. (ii) Bereavement counseling also extends to employees of SNF. It is not feasible to expect a hospice agency to have individual bereavement plans on each employees of SNF who cared for deceased person. Please delete this sentence.
   b. (ii) The proposed plan to extend bereavement services to residents and employees of SNF/NF/ICF/and MRs "when appropriate and identified in the bereavement plan of care. Hospice care and bereavement support of individuals and families directly affected by personnel loss will be significantly diminished or diluted. Allow individual hospices the flexibility to offer support to any SNF/NH/ICF/ and MR on an as needed basis when contracted by that institution.
   c. Leave spiritual counselor.
   d. Suggest that language be deleted and replaced with "*consistent with the patient's and families' wishes and the willingness of the designated counselors to respond.*"

418.66 Condition of Participation: Nursing requirements- waiver of requirement that substantially all nursing services be routinely provided directly by a hospice

a. There is a problem of accessing the waiver for nursing throughout the country. CMS regions do not understand the process and limit access to hospices because of this. We would like the process to be more user friendly. We also would like clarification as to who is eligible for the waiver, rural/urban. With the nursing shortage there is a need for the waiver in urban areas as well as rural.
b. No one utilizes the nursing waiver.
c. Everyone is in agreement that they should remove the "non-urbanized area".

418.72 Condition of Participation: Physical therapy, occupational therapy, and speech language pathology

a. We request dietitians added to the list of non-core services.

418.76 Condition of Participation: Home health aide and homemaker services

a. While it seems that there is a significant expansion of the requirements and qualifications for home health aides and homemakers, the regulations written in the home health conditions of participation are written out here and cited by number in the current COPs.
b. Need assurance that this does not indicate 24-hour care.

1. (a) Standard: Home health aide qualifications
    a. Please provide a definition of homemaker services.
2. (c) Standard: Competency evaluation
    a. This standard should add the word "aide" after home health.
3. (e) Standard: Qualifications for instructors conducting classroom supervised practical training, competency evaluations and in-service training
    a. We propose to add the words "…Of which must be in *hospice* or home health care…" to this standard.
4. (f) Standard: Eligible training organizations
    a. We propose to substitute "hospice" for the words "home health agency" in the beginning of this standard.
5. (g) Standard: Home health aide assignments and duties
    a. Hospices would like to defer this to state law. Home health aides are not allowed to assist with medications according to state law.
    b. (2) We would like this to be more fluid, if the care is outcome driven there should not be a need for a physician's order. The IDT should have the authority to decide when the patient needs the services of a home health aide. We would like clarification on this standard. We request that the IDG should have the authority to determine when the patient needs the services of a home health aide, and that no physician order is required.
    c. (iv) We would like clarification regarding home health aides assisting with administering medications.
6. (h) Standard: Supervision of home health aides
    a. What is meant by therapist? Please define.
    b. Home health agencies have 60 days to observe and assess each aide.
    c. (i) HHA supervision should not be 28 days but should be done annually. This is more stringent than Home Care Regulations (60-day HHA supervisory visit while HHA is present is only in "non-skilled cases." Hospice is Skilled Care, therefore the 60-day supervisory visit should not even apply to hospice because home care does not have to do it if it is a skilled patient.).
    d. The length of stay should not be a factor if the assessment is of the aide and not the patient. This is a human resource issue and the assessment would go in the personnel file rather than the clinical record. Ongoing competency assessments should take care of this issue.
7. (j) Standard: Homemaker qualifications
    a. Remove "a qualified homemaker is a home health aide." Many hospices use HHA and Volunteers for homemaker duties; do not want to lose ability to have a volunteer to perform this function.

418.78 Condition of Participation: Volunteers

1. (b) Standard: Role
    a. (b and e) Remove "day to day" so special events that might only occur 1 time a year can be included in the calculation of Administrative Time. (b) Takes away flexibility of dates for volunteers and may effect recruitment and selection of volunteers. Leave as it was…and/or.
2. (e) Standard: Level of Activity
    a. Refer to comments on (b).

418.100 Condition of Participation: Organization and Administration of services

1. (a) Standard: Serving the hospice patient and family
    a. Instead of "must ensure" use "*must work*".

b. Replace "desires" with "*goals*" or just stop after "*needs*". Suggested wording would be "(2) *That each patient experience hospice care that is consistent with patient and family needs and goals. (3) Where the patient and family are not in agreement as to the election and plan of treatment, the hospice will identify and list the group of individuals to whom (1) shall apply.*"

2. (e) Standard: Professional management responsibility
   a. Please change to "*requiring supervision of services*".
   b. We suggest that the language of the preamble, particularly "*supervisory responsibility of services"* [not staff] *and "by qualified personnel*" rather than personnel having "at least the same qualifications as hospice employees."
      1. From the preamble: "This standard would require written agreements for services furnished under arrangement, and would require that the hospice retain professional management and supervisory and financial responsibility for all services that are provided to the patient and family. The hospice would be required to ensure that all services provided are authorized by the hospice, are furnished in a safe and effective manner by qualified personnel, and that items and/or services specified in that plan of care are provided."
   c. The term "arrangements" is limited to arrangements under which receipt of payment by the hospital. Critical access hospital, skilled nursing facility, home health agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges liability of such individual or any other person to pay for the services.
   d. Replace "supervision" with "*oversight*" under the notion that the actual supervision of the employees would be by the employer with whom the arrangement is made and the oversight would include the employer and employees.
   e. We request a wording change in the first sentence to read "*must retain administrative and financial management, and supervision oversight of staff and services for all arranged services ...because the actual supervision of the staff would be done by the contracting agency.*"

3. (f) Standard: Hospice Satellite locations
   b. We would like a consistent policy across CMS Regions in defining and approving satellite locations.
   c. Clarify Medicare appeals process §498.3.

<u>418.102 Condition of Participation: Medical Director</u>

a. The condition states, "who is either employed by, or under contract with, the hospice." Is it an oversight that medical directors who are volunteers were not included? Would a volunteer medical director also need to be under contract?
b. We propose that when the medical director is not available that a physician is designated by the hospice.
c. The last sentence is an example of how the role of the medical director/physician seems to supercede the IDT of which the medical director is a member.
d. Take out "and"; replace with "or". No need to contract for volunteer MD. Add "the medical director or physician designee and/or the hospice team will coordinate with other physicians..." OR- The MD or physician designee with IDT coordinates with other physicians and health care professionals.
e. We request that there needs to be ability for hospice to contract with an entity for a physician to serve as medical director, rather than with an individual physician.

1. (a) Standard: Initial certification of terminal illness
   a. We ask for clarification/discussion of criteria for determining appropriateness and eligibility.
2. (b) Standard: Recertification of the terminal illness
   a. We ask for clarification on what documentation the medical director would look at to review "the patient's and family's expectations and wishes for the continuation of hospice care."

3. (c) Standard: Coordination of medical care
    a. Removal of "Medical Director or physician designee is also responsible for directing the hospice's quality assessment and performance improvement program.
    b. Please clarify the difference between a patient's "medical care" and "hospice care".
    c. In light of the scope of the QAPI requirements and the fact that many medical directors are part time or volunteers, what is expected in terms of the medical director "directing" the hospice's QAPI program? Why not expand this to "or other qualified professional" so that a full time employee could be hired to do most of the work.
    d. Of these tasks, the review of records and certification of terminal illness and provision of care in the absence or unavailability of the attending physician can only be done by the Medical Director. The others require some oversight by the Medical Director, but can be done by other staff, with general direction and review coming from the Medical Director. Indeed, in most hospitals, the QA/PI functions are usually coordinated by nursing staff with oversight from the Medical Staff when issues arise and at intervals approximating quarterly. Coordination of care is more nebulous, since some of it clearly requires conversation among providers, but some of it can be done at the office staff level.

418.104 Condition of Participation: Clinical records

a. Electronic medical records are costs prohibitive to small hospices- not only the hardware (laptops) but also the software costs or rental.
b. We would like a clarification for "accurate".

1. (a) Standard: Content
    a. Since patient's rights condition of participation is intended to replace the current condition, could you clarify what is required here?
    b. What do they mean by authorization? Authorization to release health information? Authorization to disclose information? The only authorization currently required from patients may fall under HIPAA privacy regulations but this is not something that would be required of every patient and therefore not included in every clinical record.
2. (b) Standard: Authentication
    a. This standard comes from the hospital conditions of participation. Home care is much broader than hospital care. More information is needed as to how this standard can be realistically applied to hospice.
    b. The preamble states that a similar requirement is in the conditions of participations for hospitals. Our concern is that home care is so broad that it may not be feasible to completely comply with this standard. For example, does this standard apply to all consulting or covering physicians?
    c. Note in the comments that NF and HHA do not have such a standard, only hospitals, whose rule says:
       482.24(c) Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.
        (1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.
            (i) The author of each entry must be identified and must authenticate his or her entry.
            (ii) Authentication may include signatures, written initials or computer entry.
3. (d) Standard: Retention of records
    a. We would like this to follow the HIPPA requirements for records retention.
    b. Recommend 6 years to be in compliance with HIPPA.
4. (e) Standard: Discharge or transfer of care
    a. This is in conflict with "minimal necessary" disclosure; remove the clinical record to

be sent.

b. Sending a copy of the patient's clinical record if the patient transfers, revokes or is discharged is particularly onerous, not necessary since the discharge summary requirements are comprehensive and receipt of the entire printed clinical record (sometimes hundreds of pages) is not likely to be welcomed by facilities or attending physicians. The release of information should follow the Minimum Necessary Standard in HIPAA.
c. Patients care plan appropriate for transfer but not for discharge.
d. In this Standard the description of the discharge summary is thorough—perhaps providing a copy of the discharge summary to the new facility and the attending physician will be adequate.
e. We are concerned with sharing non-medical information, i.e. family information
f. Please add: *When electronic medical records are available, sharing of the discharge summary and/or medical record through an electronic format will be preferable. The electronic sharing of records may include access to the record through secure internet access or other electronic access available through transferable data storage media. The record should be in an industry standard file format. If the recipient is unable to utilize the electronic files, a paper copy will be provided.*

<u>418.106 Condition of Participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment</u>

a. We request the language from 418.110(m) be inserted in here—so that the more comprehensive language would apply the behavior of the hospice as a whole (and so the hospice could import the service into an inpatient setting instead of having to establish it there).

1. (b) Standard: Controlled drugs in the patient's home
   a. Please remove the word "collecting" out of this sentence. We also question using the term "potential dangers" with controlled substances. Hospice has worked for years to dispel myths associated with narcotic use with terminally ill patients. Please remove potential dangers of controlled substances;
   b. Please add a definition for "tracking meds"
2. (c) Standard: Use and maintenance of equipment and supplies
   a. When a hospice contracts for DME isn't it the vendor's responsibility to have repair and routine maintenance policies? And where it is a dealer with a CMS supplier number, can't the hospice assume it meets this requirement since it is a general CMS requirement, too?
   b. Please use the following language:

      The hospice, either directly or through contractual agreement, ensures that there is a process for providing routine and preventive maintenance of equipment and that the equipment is safe and works as intended for use in the patient's environment. This may occur directly or through contractual arrangement. (Addition: "either directly or through contractual agreement" clarifies the responsibilities of contractors if they are used to supply medical equipment.)

<u>418.108 Conditions of Participation: Short-term inpatient care</u>

a. Add *"psychosocial/family crisis/issues"*.
b. This introduction should define the care as "care provided by the hospice on an inpatient basis in a facility that meets the requirements of…and then lists the provider standards in (a) and (b). Then it should say that inpatient care for symptom management and pain control and respite may be provided in any of these facilities. Paragraph (a) should note that pain control and symptom management would be done on an inpatient basis either because of the specific need for the staff and equipment available there or because of the inability of the hospice and/or the patient's caregivers to assure that the services are properly provided in the home. Paragraph (b) would discuss respite and the five-day limit.

1. (a) Standard: Inpatient care for symptom management and pain control
   a. Include same language as 418.108. Respite- NO RN. GI—YES RN.

b. The word "approved" should be replaced with "*certified.*"

2. (b) Standard: Inpatient care for respite purposes
    a. Define Medicare/Medicaid approved nursing facility? Does this mean "certified?"
3. (c) Standard: Inpatient care provided under arrangements
    a. Clarify whether or not the hospice is required to have a copy of the patient's entire inpatient clinical record in its possession or whether it can arrange with the inpatient provider to retain the records on its behalf until required. Why require duplication of records if not needed? If a surveyor needed them, they could be requested.
    b. The hospital discharge summary should be sufficient for the hospice to ensure continuity of care.

418.110 Condition of Participation: Hospices that provide inpatient care directly

1. (a) Standard: Staffing
    a. Is it permissible for hospices to ensure the 24-hour coverage in a nursing facility by providing nurses for shifts not covered by the nursing facility?
2. (b) Standard: Twenty-four hour nursing services
    a. If skill is a concern than offer a certification for inpatient hospice nursing and put as a criteria to work in hospice house or facility.
    b. Clarify what "nursing services" means. We suppose that it means services of both RN and LPN/LVN as it does in the NF requirements.
    c. Is there a minimum requirement of services or qualifications?
3. (c) Standard: Physical environment
    a. Define and provide examples of "equipment failures" that would be required to be reported? We would also like to know where the section (ii) originated.
4. (f) Standard: Patient rooms.
    a. Add this to the end of (iv): except during community disasters and/or evacuations.
5. (m) Standard: Pharmaceutical services
    a. Section (m) should also be included in 418.106 as an indication that these are requirements laid on the hospice as a whole, not just on an inpatient basis. (m) Should cross-refer to the earlier standard.
    b. Clarify whether or not patients are allowed to bring prescription drugs from home into a facility.
6. (n) Standard: Pharmacist
    a. (iii) We may suggest adding "*if required by law*" to the end of this paragraph.
7. (o) Standard: Seclusion and restraint
    a. Please remove drug/chemical restraint language- opening the door to surveyor interpretation.
    b. Suggested changes underlined: Bed rails are not included in this definition of restraint if used for the safety of the patient or to assist the patient in independent functioning. A drug used, as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a hospice patient's hospice medical or psychiatric condition. Seclusion is the restricted confinement of a person alone in a room or an area where a person is physically prevented from leaving.
    c. Add the word "*unpredicted*" before death.
    d. We would like clarification on (7) as to why this has to be reported to CMS and to what office at CMS?

418.112 Condition of Participation: Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities

a. Please define the term "facility". This section should specifically apply only to Medicare and Medicaid participating facilities. Also, this condition cannot successfully be implemented until there is in the SNF/NF requirements a parallel condition that conforms their requirements. We recommend that the effective date of this section be delayed until the companion section is enacted or that it be at least incorporated by reference into the SNF/NF requirements. We understand that the nursing home COPs will add a section on nursing homes and hospice care. Does this condition match the requirements that will be proposed for nursing homes?

b. We ask that CMS work with surveyors on this issue and that hospices be allowed some leniency until the nursing facility regulations are complete.

1. (b) Standard: Professional management
   a. Add "*hospice*" after "inpatient".
   b. Please provide some information regarding how this standard is or is not related to nursing home regulations. We assume that this means that the hospice must avoid making assumptions about care provisions and specify the services to be provided by the facility and the ones to be provided by the hospice and the processes for management and routine communication.
2. (c) Standard: Core Services
   a. Add "*work*" behind "medical social".
3. (d) Standard: Medical director
   a. We are concerned that the requirements of this standard may cause unnecessary strain in the relationship between the hospice and the facility. Intent good, but not realistic- Please delete.
   b. Explain why in this instance (as well as elsewhere in the proposed regulations) the Medical Director appears to be separated out from the rest of the IDT? We believe that the best language would be to require that the IDT assume this duty through a designee of its choice, either an MD or a nurse.
   c. Is it permissible for the NF Medical Director to also be the Hospice Medical Director?
   d. We are concerned that the requirements in this standard may cause unnecessary strain between the hospice and the facility. Rather, care coordination between members of the hospice IDG and the nursing home team who are likely to have more daily contact with the patients should be encouraged.
4. (e) Standard: Written agreement
   a. Is the written consent of the patient to be part of the facility/hospice contract?
   b. We would like clarification of a life threatening condition other than the patient's hospice terminal diagnosis.
   c. States vary in what they consider included in the room and board rate and what their responsibility is in the provision of room and board. How does this impact this Standard? Will the room and board definition in the State Operation Manual be changing in relation to the hospice regulations?
   d. Add "*hospice*" before " inpatient care". The phrase would read: *"arrangements necessary for hospice inpatient care…"*
5. (f) Standard: Hospice plan of care
   a. Needs clarification of "all".
   b. Please clarify who is expected to review the plan of care, hospice, nursing facility, or both?
   c. We would like a definition or clarification on what is meant by "all caregivers".
   d. We are concerned that this standard gives the hospice authority over the nursing staff decision making and may be contrary to the current nursing home requirement that nursing home staff be responsible for everything that happens.
6. (g) Standard: Coordination of services
   a. Are we correct in assuming that physician orders refers to the hospice physician orders?
7. (h) Standard: Transfer, revocation, or discharge from hospice care
   a. For some facilities, discharge from the hospice could mean the person may no longer reside in the facility. Please provide some clarification of this standard including how compliance would be audited. Why not change "does not directly impact" to "may not affect"?
8. (i) Standard: Orientation and training of staff
   a. We are concerned that facilities may be inundated with hospice in-services if they have contracts with multiple hospice providers. Reword this standard to state, *"must assure orientation of facility staff"*.

418.114 Conditions of Participation: Personnel qualifications for licensed professionals

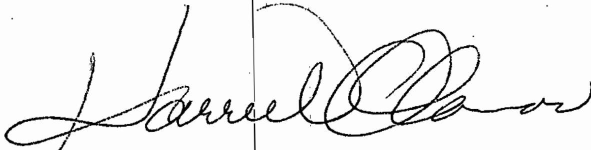
a. Is the implication here that non-degreed social workers can be hired and work as social workers because they are licensed by the State? If so, the effect of going to State licensure here is to lower the requirement for social workers that has been in this rule up to now. We question whether this is appropriate, given the importance of social workers in this context and we believe CMS should consider reinstating the current requirement.

1. (c) Standard: Personnel qualifications when no state licensing certification or registration requirements exist.
   a. We request that the current social work requirement should be retained.: *A social worker is a person who has a baccalaureate degree from a school of social work accredited by the Council on Social Work Education with one phrase changed" "A social worker is a person who has at least a baccalaureate degree..."* This will clarify and include all MSW-prepared social workers whose undergraduate degree is in another field.
2. (d) Standard: Criminal background checks
   a. Would compliance with State laws regarding criminal background checks suffice for compliance with this standard? We agree with this provision only if there is an established mechanism available to hospices by which the checks may be made. If there is not, this requirement creates open-ended jeopardy for hospices with no prospect that they can actually meet the requirement effectively.
   b. We are concerned by the phrase "before employment at the hospice". There should be some flexibility in hospice policy about what the hospice can do with the employee until the results of background check are returned, if the process in the state is lengthy.
   c. Another area of concern is whether contracted employees would be the responsibility of the hospice. A criminal background check should be the responsibility of the contracting agency as part of the written agreement.

We appreciate this opportunity to provide comments to CMS regarding the proposed changes in the Conditions of Participation for Hospice. The comments provided are from our members—hospice providers, hospice professionals and individuals supporting our missions of education Hoosiers about end of life care. The comments are made to assure open access for all to quality of end of life care.

Thank you for your consideration of our comments.

Sincerely,



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July 22, 2005

CMS
Room 445-G Hubert H. Humphrey Bldg.
200 Independence Avenue SW
Washington, DC 20201

Dear CMS:

Re: CCMS-2844-P-Medicaid and Medicaid Programs: Hospice Conditions of Participation Comments

The Board and members of the Illinois Hospice & Palliative Care Organization appreciate the efforts of CMS in revising the purposed conditions of participation that hospice must meet in order to participate in the Medicare and Medicaid programs. We would like to offer the following comments for your consideration as you finalize the conditions and prepare the interpretative guidelines.

418.3 Condition of Participation: Definitions

1. Please add definitions for the following:
   a. Initial Assessment
   b. Comprehensive Assessment
      Please clarify requirement by giving a definition.
   c. Counseling Services
      We request the definition of Counseling Services include bereavement counseling
   d. Dietitian
      We propose the following definition: *Dietitian means a person who is registered by the Commission of Dietetics' Registration or the American Dietetic Association.*
   e. Facility
      We propose the following definition: *Facility means a place where the patient resides where care is provided for the patient*
   f. Hospice patient
   g. Social Worker
      Please use language from the current COP's.
   h. Nursing Services
      Please add that nursing service are provided by a licensed nurse, and provide further clarification in the preamble to clarify that nursing services are at times delegated to a home health aide.
   i. Homemaker
      Please include clarification of the role and qualifications of the homemaker
   j. Patient's residence
      We propose the following definition: Patient's residence means a house, apartment, SNF, NF, ICF/MR, assisted living facility, shelter, foster home or any other location where the patient lives.

k. Family members
We propose the following definition: *Family members means the person(s) identified as having a significant role in the patient's life.*

2. Please clarify the difference between Plan and Care and Care Plan.
3. Attending physician
   a. Please add the following to the definition of attending physician: "*the hospice medical director or nurse practitioner may also act as the patient's attending physician*" based upon 1812(d)(2)(A) Except as provided in subparagraphs (B) and (C) and except in the exceptional and unusual circumstances as the Secretary may provide, if an individual makes such an election for a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made under this title except...physicians' services furnished by the individual's attending physician (if not an employee of the hospice program)" The regulations should somewhere note that is a permissive section relating to the patient so that the attending physician's input is required if (1) the patient has one, and (2) the physician is willing to participate See also section 418.54 (b)
   b. Please clarify the difference between "covering physician" versus "Physician designee". *A covering physician is a physician acting on behalf of the attending physicians. A physician designee is a physician acting on behalf of the hospice medical director.*
   c. (1, (i), (ii)): Please delete "and surgery".
   d. Please add "Nurse Practitioner may also act as the patient's attending physician."

4. Bereavement Counseling.
   a. Please note that bereavement is not limited to after death but includes anticipatory grief and family members who have had bad death experiences in the past may need attention from bereavement counselors pre-death.
5. Clinical Note
   a. Please add the word *spiritual* to "any changes in the physical or emotional condition" at the end of this definition. Please clarify the difference between progress note or clinical note. Please define the requirements for each.
6. Drug Restraint
   a. This definition needs to be clarified because some medications that may be viewed, as a chemical restraint in some instances may be normal patient care protocol in hospice.
7. Employee
   a. Please adhere to the HIPAA language and use of workforce.
8. Licensed professional
   a. Please add dietary therapy to this definition.
9. Physical restraint
   a. Please add the phrase "or adjacent" as follows: "*...or equipment attached or adjacent to the patient's body....*"
10. Representative
   a. Please add after "...courts of the state" the words "*or by common law within the State*" in order to take care of situations that are permitted but not statutory. See this from NF Rules: (4) in the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by state law.

<u>418.52 Condition of Participation: Patient's rights</u>

a. Hospice providers and professionals have a real concern about information overload of patient/families. The admission process will take even longer (thus wearing out the patient more) if we have to demonstrate not only disclosure, but understanding of the bill of rights pertaining to advance directives and P/P for medication tracking and disposing. What about the consents we mail- how is that affected? Will we be able to do this by phone?

b. Burden estimates are underestimated by far. Estimated by nurses to be triple the estimates in the proposed COPs. Ex. 15 minutes to document and resolve a complaint? That can take days. Ex. 5 minutes to explain payer and extent to coverage??? Ex. Comprehensive assessment.

1. (a) Standard: Notice of rights
   a. Please remove "during the initial evaluation visit" and make reflective of the home health care regulation
   b. In some parts of the state there are many dialects and it would be impossible to provide written rights in the patient's language. Please change to relate, so that the patient understands their rights via an interpreter, a family member or other who understand the rights.
   c. We request that the right for the patient to be involved in their plan of care be added.
   d. We believe that informing the patient of drug policies and procedures at the time of admission will be confusing to the patient and primary caregivers, especially disposal policies. Patient and their caregivers are given a tremendous amount of information at the time of admission and it is impossible to retain all of the intricacies of hospice. We suggest that notice of drug policy/tracking should be addressed during the admission process-this information can be provided in the section where explanation of equipment and meds are in admission packet.
   e. We believe that there needs to be clarification of who tracks, how they track, what exactly needs to be tracked and what would the surveyor be looking for? We suggest that tracking and disposal of drug policies are demonstrated during the 4-calendar day assessment period.
2. (b) Standard: Exercise of rights and respect for property and person
   a. Please include wording that a patient has the right to refuse treatment. Proposed wording could be: *The patient has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive.*
   b. Add "*and practice.*"
   c. We suggest that the CMS language from the Home Health Conditions of Participation may be more appropriate. HHA COP Requirement 484.10 may be more appropriate to the hospice/home environment: *The Hospice must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the hospice, and must document both the existence of the complain and the resolution of the complain.*
   d. We recommend that the right to keep the patient's attending physician be added.
   e. We recommend that the patient maintains the right to be involved in their plan of care.
   f. We recommend that a change be made to the complaint policy, which includes the following: an overall review of the complaint policy and its applicability to hospice; and a change to (5) five days from the discovery of the incident.
3. (e) Standard: Patient liability
   a. How does this relate to the Advance Beneficiary Notice requirement? The ABN requirement applies whenever the patient wants something the hospice doesn't think is covered but is willing to pay for it (e.g. Deluxe DME, or HH Aide beyond the POC) The ABN is given to the patient so that (1) CMS know the beneficiary is protected, and (2) it can determine if the service should have been covered.
   b. LIABILITY/ASIGNMENT OF PAYMENT. Before care is initiated the patient is informed verbally and in writing, and in a language that he or she understands that services provided by hospice will be billed to: Medicare, Medicaid, Insurance, another third party payer. Patient is informed that, if applicable, patient may be asked to pay deductibles, co-payments and any other amounts due after payments on patient's behalf have been made by any and all third party payers. Hospice related services not approved by the hospice interdisciplinary care team, would be billed to patient.

418.54 Condition of Participation: Comprehensive assessment of the patient

a. The words "includes but is not limited to" may be too broad and we may need to modify.
b. Change "care" to "assessment" in the last sentence so we can include items not related to the terminal illness that we would still want to assess.

1. (a) Standard: Initial assessment
    a. Please clarify the term "initial assessment" Is this an initial assessment of immediate needs and if so the RN may not be the most appropriate person to complete this because the immediate needs may not be physical in nature? The word "RN" should be replaced by "*a member of the hospice interdisciplinary team*".
    b. The RN should be there within 24 hours following a referral (with the family's permission) but a Social Worker or Chaplain can go before the RN to discuss hospice service.
    c. Add language "*24 hours upon request by patient or representative*". We recommend that "physician's order for care" be changed to "*physician's certification of care.*".
    d. We request that the words "ordered by the physician" be changed to "*ordered by the physician or requested by the family.*"
    e. We propose language for a Comprehensive Assessment that would include, at a minimum, an in person assessment by the nurse and social worker within the first 7 days of care. These documents, as well as any other generated by other IDT members would form the Comprehensive Assessment. We would not be expected to complete the full assessment and data element collection of patients that did not live this long.
2. (b) Standard: Time frame for completion of the comprehensive assessment
    a. Comprehensive assessment should be included in the definitions; 4 calendar days should be replaced with "7 calendar days or upon a time frame agreed to by the patient or authorized representative."
    b. "Comprehensive assessment" is not clear. Does this mean each team member completes an assessment or can the RN complete the comprehensive assessment? If only the RN completes the comprehensive assessment then is it really comprehensive because the perspective of other core services are not represented? Is the comprehensive assessment a process or a document?
3. (c) Standard: Content of comprehensive assessment
    a. The content of the comprehensive assessment is focused on needs- this would be the prelude to the plan of care.
    b. The comprehensive assessment identifies physical, psychosocial, emotion, and spiritual needs including a bereavement risk assessment and a review of the patient's prescription & OTC medications. Look at comprehensive assessment as a process which starts on the initial nursing visit including the plan of care…all disciplines review the plan of care on each visit, assessing and evaluating outcomes and revising as needed. On going process which involves all disciplines.
    c. We request that this comprehensive assessment and care planning be limited to the care needed for the management and palliation of the terminal illness.
    d. The statute (SEC, 1862, (42 U.A.C. 1395y((a) says: "Notwithstanding any to other provision of this tile, no payment may be made under Part A or Part B for any expenses incurred or items or services___
       (1)
       (A)
       (B)
       (C) in the case of the hospice care, which are not reasonable and necessary for the palliation or management of terminal illness.)"
       The statute limits coverage. This language is OK for the assessment but not for a terminal plan. This should be clarified in the regulation—comprehensive assessment but duty for care plans limited to management and palliation.

4. (d) Standard: Update of the comprehensive assessment
    a. We request that the update closest to the recertification timeframe be acceptable as an update at the time of recertification.
5. (e) Standard: Patient outcome measures
    a. We recommend the development of meaningful outcome measures at first IDG after admission. Order and develop meaningful measures.
    b. Outcome measures should be part of the ongoing process of the care plan not the comprehensive assessment. Eliminate comprehensive assessment- go to comprehensive care plan.

<u>418.56 Condition of participation: Interdisciplinary group care planning and coordination for services</u>

a. Apply the concepts of "initial" and "comprehensive" to care planning rather than assessment. Base an initial plan of care on the admission assessment completed by a nurse and develop a comprehensive plan of care based on assessments by all disciplines. Updates to the plan of care are then based on ongoing assessment visits made by all disciplines.

1. (a) Standard: Approach to service delivery
    a. One IDT does not establish governing policies of the day-to-day care. An administrative team that is generally interdisciplinary establishes policies and oversees day-to-day provision of hospice care and services.
    b. Why was this IDG team role narrowed from the original COPs? Should say "(iv) a counselor, including pastoral, clergy, spiritual, or other counselor." The language in the law is:
       "B) has an interdisciplinary group of personnel which—
       includes at least--
       (I)one physician (as defined in subsection
       (r)(1),
       (II) one registered professional nurse, and
       (III)one social worker,
       Employed by or, in the case of a physician described in sub clause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor, " should you cite the law.
    c. (1.i): Hospice medical director and attending physician can be one in the same.
    d. A social worker, chaplain, MD can coordinate and facilitate the team meetings and care. The RN can still be the "care manager".
    e. What does this section of the standard mean?
    f. We request that the language in (iv) be consistent wit the statutory provision for the IDG—"a pastoral, clergy, or other counselor"
2. (b) Standard: Plan of care
    a. How should acceptance of the care plan by the family be noted? Can it be done by omission; that is, they are not disagreeing?
    b. A patient has a right to self-determined life closure—families do not need to agree.
3. (c) Standard: Content of the plan of care
    a. We request that after "*includes*," the regulation should read "*services for the palliation and management of the terminal condition, including…*"
    b. (c.2) Omit the word detailed so patients can have flexibility in their number of visits.
    c. Family should understand and be involved but agreement should come from the patient or legal representative. Delete the word agreement out of this sentence. The family may not be in agreement with the plan of care, but the patient may be in agreement.
4. (d) Standard: Review of the plan of care
    a. Reword to read, "The interdisciplinary team (in collaboration with the individuals, attending physician to the extent possible…"
5. (e) Standard: Coordination of services
    a. The language should allude to sharing of information with non-hospice providers, who are sharing the care (e.g., an ERSD dialysis facility for a cancer patient who gets dialysis for kidney failure).

b. (4): Provide for and ensure the ongoing sharing of information between all disciplines providing care and services in the home, in outpatient settings, and in inpatient settings, irrespective whether the care and services are provided directly or indirectly under arrangement.
c. We recommend expanding the role of IDT leader to include the social worker.
d. We suggest adding some wording such as: "Sharing of information may be accomplished through paper documents or electronic media, or telephonic or in person meetings, or some combination of these methods."

418.58 Condition of Participation: Quality assessment and performance improvement

a. 5 hours a year implementing performance improvement activities??? Hardly enough. (p30872) Where did they get hourly employee rates? Too high for some and too low for other hospices. 5 minutes to document HHA requirements???

1. (a) Standard: Program scope
    a. Include language that the hospice defines adverse events by organizational policy based on accepted such as JCAHO NPSG, etc. Death is not an adverse event for hospice. What is meant by adverse events? Please define adverse event. Adverse event should be defined as unexpected death or an incident that leads to a serious consequence .It's important to identify hospice adverse events. An examples of adverse event would be s a physician who refuses to follow advance directive.
    b. There is some confusion throughout the document as to the language regarding data elements. We would like language used throughout the document that is consistent with Quality Assessment and Performance Improvement Programs.
2. (b) Standard: Program data
    a. We request that the governing body staff provide oversight of the agency's performance improvement program, and delegates responsibility to qualified hospice employees who report improvement activities and findings back to the governing body.
3. (e) Standard: Executive responsibilities
    a. Change to: *The governing body is responsible for* <u>*monitoring*</u> *the following…*

418.60 Condition of Participation: Infection Control

a. Do we have documentation that infection control is a significant enough problem? To focus on it to the extent listed, which does not seem practical. Can we do this based on need- that is an infection of the patient or any family member; standard precautions for biological wastes and other basic precautions is reasonable to expect for all patients.

1. (a) Standard: Prevention
    a. The standard of practice in hospice care is that some infections such as pneumonia are expected and may not be treated. There is concern regarding how this will be interpreted at the survey level. We suggest giving the agency the latitude to use and treat the patient according to direction of IDT and patient/family's needs. (b.2.ii) This is counterproductive to the hospice mission; please delete this item.

418.62 Condition of Participation: Licensed professional services

a. (b) Please add the word "*hospice*" after "patient's".

418.64: Condition of Participation: Core services

a. Include continuous care as a circumstance when nursing staff can be contracted.
b. If we are allowed to contract we can then develop relationships with specific agencies and provide ongoing training to their staff. These very agencies can then serve many hospices.

1. (b) Standard: Nursing services
    a. There is not a clear definition of what is included in nursing services-RN, LPN, and LVN. Please include a definition in the definition section?
2. (d) Standard: Counseling Services
    a. We provide bereavement services to facilities who have taken care of patients through debriefing sessions, a special remembrance service just for staff in honor of that patient (especially our children who have died), we also send them cards and call them just like

we do for our family members. Sometimes we provide support to the facilities prior death to prepare them and give then an opportunity to talk about fears, hopes and the dying and death process. Most facilities are grateful for the calls and seminars and find them to be very helpful, educational and supportive.

b. Replace this section with "facilitate visits by local clergy, pastoral counselors, or other spiritual supports that are consistent with the patient's and family's wishes and the availability of community resources.

c. (d.1.iii) Please be clearer about how we are to do this.

418.66 Condition of Participation: Nursing services: Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice

a. There is a problem of accessing the wavier for nursing throughout the country. CMS regions do not understand the process and limit access to hospices because of this. We would like the process to be more user friendly. We also would like clarification as to who is eligible for the wavier, rural/urban. With the nursing shortages there is a need for the wavier in urban areas as well as rural.

418.72 Condition of Participation: Physical therapy, occupational therapy, and speech-language pathology

a. We would like dietitians added to the list of non-core services.

418.74 Condition of Participation: Waiver of requirement- Physical therapy, occupational therapy, and speech-language pathology, and dietary counseling

a. 24-hour pt/ot/speech available provided as needed?- How often do we use PT, let alone at 2 a.m.? Unrealistic! They are not available to us 24 hour a day. Even acute care centers do not have 24-hour therapies- they are not urgent nor emergent needs.

418.76 Condition of Participation: Home health aide and homemaker services

a. Change Home Health Aide to the universal label of "Certified Nursing Assistant".

1. (a) Standard: Home health aide qualifications
    a. We would like a definition of homemaker services.
2. (c) Standard: Competency evaluation
    a. We request that this standard should add the word "aide" after home health.
3. (e) Standard: Qualifications for instructor conducting classroom supervised practical training, competency evaluations and in-service training.
    a. We would propose to add the words "*...Of which must be in the hospice or home health care...*" to this standard.
4. (f) Standard: Eligible training organizations.
    a. We would propose to substitute "hospice" for the words "home health agency" in the beginning of this standard.
5. (g) Standard: Home health aide assignments and duties
    a. Hospices would like to defer to state law.
    b. We would like this to be more fluid, if the care is outcome driven there should not be a need for a physician's order. The IDT should have the authority to decide when the patient needs the services of a home health aide. We would like clarification on this standard.
    c. We would like clarification regarding home health aides assisting with administering medications.
    d. Nursing assistant's assessment, supervision and coordination should be exclusive to a registered nurse.
    e. (2.i) Either delete or change to "ordered by interdisciplinary team."
    f. (4) This statement delineates specifics the nursing assistants are not capable of prioritizing. It is safer practice for patients/families for nursing assistants report any and all changes in a patient's condition or noticeable issues with family dynamics.
6. (h) Standard: Supervision of home health aides
    a. What is meant by therapist?
    b. Home health agencies have 60 days to observe and assess each aide.

c. The length of stay should not be a factor in the assessment of the aide and not the patient. This is a human resource issue and the assessment would go in the personnel file rather than the clinical record. Ongoing competency assessments should take care of this issue.
d. Human resources function to monitor competency of CNA. Change "on-site" and "direct" to "*indirect supervision*".
e. Use the standard of the Health Agency COPs; have 6 months to observe and assess each HHA.
f. Delete qualified therapists.
g. Make evaluate CNAs' delivery of care.
h. Delete every 28 day on site visit and we recommend yearly competency assessment. On the every 14-day nursing onsite visit, evaluate services provided.
i. Can a physician do a CNA supervisory visit as well as an RN? Any employee can act perfect while you are there; what are we trying to find out with these visits? If you have had a CNA several years, why do you need to supervise every 2 weeks? Could we do the proposed for the first months or year of employment, and spot check later or as needed if there are problems (problems defined by Medical Director, RN, Executive Director or other supervisory staff as well as family complaint).

7. (j) Standard: Homemaker qualifications
   a. Delete home health aide from the paragraph.
   b. Reword Homemaker qualifications to read, "A qualified homemaker has successfully completed orientation addressing the needs and concerns of patients and families coping with terminal illness".

418.78 Condition of Participation: Volunteers

1. (e) Standard: Level of activity
   a. Maintaining volunteer involvement is important but a 5% requirement is arbitrary, based on unknown factors, and at times difficult to achieve.

418.100 Condition of Participation: Organization and administration of services

1. (a) Standard: Serving the hospice patient and family
   a. (2) That each patient experience hospice care that is consistent with patient and family needs and desires. Change the word "desires" to "goals" to emphasize the role goals play in developing and implementing the plan of care.
   b. (3) Where the patient and family are not in agreement as to the election and plan of treatment, the hospice will identify and list the group of individuals to whom (1) shall apply.
2. (e) Standard: Professional management responsibility
   a. We suggest that the language of the preamble, particularly "supervisory responsibility for services" [not staff] and "by qualified personnel" rather than personnel having "at least the same qualifications as hospice employees." The language "supervision of staff" and "at least the same qualifications of hospice staff" is an onerous responsibility for hospices and will be difficult to implement. How broadly will this be interpreted, i.e. supervise staff in nursing homes, contracted hospital, etc.
   b. From the preamble: This standard would require written agreements for services furnished under arrangement, and would require that the hospice retain professional management and supervisory and financial responsibility for all services that are provided to the patient and family. The hospice would be required to ensure that all services provided are authorized by the hospice, are furnished in a safe and effective manner by qualified personnel, and that items and/or services specified in the plan of care are provided. We request the language in the first sentence be changed to read "must retain administrative and financial management, and supervision oversight of staff and services for all arranged services...because the actual supervision of staff would be done by the contracting agency.
   c. (w)(1) The term "arrangements" is limited to arrangements under which receipt of payment by the hospital, critical access hospital, skilled nursing facility, home health

agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.

d. Replace "supervision" with "oversight" under the notion that the actual supervision of the employees would be by the employer with whom the arrangement is made and the oversight would include the employer and employees.

3. (f) Hospice satellite locations.
   a. We request that a CMS satellite location standard be implemented consistently across CMS regions.
4. (g) Standard: In- service training
   a. Assess competency of PT and contracted? That's why we hire them; we are not competent to do it.

<u>418.102 Condition of Participation: Medical director</u>

a. The condition states, "Who is either employed by, or under contract with, the hospice." Is it an oversight that medical directors who are volunteers were not included? Would a volunteer medical director also need to be under contract?
b. We propose that when the medical director is not available that a physician is designated by the hospice.
c. The last sentence is an example of how the role of the medical director/physician seems to supersede the IDT of which the medical director is a member. Please replace the last sentence with "the medical director is a member of the IDT and participates in ensuring that each patient received hospice care that is consistent with evidence based practice and reflects hospice policy."
d. Medical director does not need to be a separate condition of participation. These responsibilities can be incorporated into physician services in the core services section.

1. (a) Standard: Initial certification of terminal illness
   a. We ask for clarification/discussion of criteria for determining appropriateness and eligibility.
   b. We request that the hospice be responsible for designating who will take the medical director's place when he or she is not available
2. (b) Standard: Recertification of the terminal illness
   a. We ask for clarification on what documentation the medical director would look at to review "the patient's and family's expectations and wishes for the continuation of hospice care."
3. (c) Standard: Coordination of medical care
   a. Please make the difference between a patient's medical care and a patient's hospice care.
   b. In light of the scope of the QAPI requirements and the fact that many medical directors are part time or volunteers, what is expected in terms of the medical director "directing" the hospice's QAPI program? Why not expand this to "or other qualified professional" so that a full time employee could be hired to do most of the work. Please delete the last sentence of this section and substitute with "the medical director participates with the interdisciplinary team in the hospice QAPI program which is directed by a qualified professional designated by the hospice governing body"

<u>418.104 Condition of Participation: Clinical Records</u>

a. How will our records mesh with hospitals, Nursing Homes, etc once EMR (electronic med record) is here?
b. Patient access to whole medical record? Could negatively affect patients emotionally.
c. Logistically, updated care plans for family and facilities will be a problem once RNs are laptops unless they carry a printer along…?
d. We would like a clarification for "accurate."

1. (a) Standard: Content
   a. Since the patient's rights condition of participation is intended to replace the current informed consent condition, could you clarify what is required here?

b. Please clarify what "authorization" is in (2). The only authorization currently required from patients may fall under HIPAA privacy regulations but this is not something that would be required of every patient and therefore not included in every clinical record.

c. Copy of the entire medical record would many times be two inches thick; from a practical standpoint if we can show we sent the critical information to show an adequate picture of the condition of patient (discharge summary, most recent plan of care, med list, last nursing visit, advanced directives is any, face sheet with reimbursement (Medicare, Medicaid, etc) numbers and info sent to us should be enough. Wasting paper and time to send back to physician what was originally sent to us. We should not forward any of the chart that is not our documents re: hospice.

2. (b) Standard: Authentication

a. The preamble states that a similar requirement is in the conditions of participations for hospitals. Our concern is that home care is so broad that it may not be feasible to completely comply with this standard. For example, does this standard apply to all consulting or covering physicians? NF and HHA do not have such a standard, only hospitals, whose rule says: 482.24(c)Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished. The author of each entry must be identified and must authenticate his or her entry. (ii) Authentication may include signatures, written initials or computer entry. We recommend that we use the COPs of Home Health Agencies regarding signature acceptance.

3. (d) Standard: Retention of Records

a. We would like this to follow the HIPAA requirement for records retention.

4. (e) Standard: Discharge or transfer of care

a. Sending a copy of the patient's clinical record if the patient transfers, revokes or is discharged is particularly onerous, not necessary since the discharge summary requirements are comprehensive and receipt of the entire printed clinical record (sometimes hundreds of pages) is not likely to be welcomed by facilities or attending physicians.

b. The release of information should follow the Minimum Necessary Standard in HIPAA. Please change the language to require a discharge summary and other records available as needed in accordance with HIPAA.

c. Please add: When electronic medical records are available, sharing of the discharge summary and/or medical record through an electronic format will be preferable. The electronic sharing of records may include access to the record through secure internet access or other electronic access available through transferable data storage media. The record should be in an industry standard file format. If the recipient is unable to utilize the electronic files, a paper copy will be provided.

d. Please delete "forward a copy of patient's clinical records to receiving hospice" and also delete at DC- the MD is to be provided a copy of the clinical record.

5. (f) Standard: Retrieval of clinical records

a. Please define access parameters for electronic and paper retrieval.

<u>418.106 Condition of Participation: Drugs, controlled drugs and biologicals, medical supplies, and durable medical equipment</u>

a. Put the language from 418.110(m) in here—so the more comprehensive language would apply the behavior of the hospice as a whole (and so the hospice could import the service into an inpatient setting instead of having to establish it there.

1. (a) Standard: Administration of drugs and biologicals

a. To document if patient is able to safely administer drugs at every team meeting is cumbersome; how about documenting if problems with drug administration are identified.

2. (b) Standard: Controlled drugs in the patient's home
   a. Delete the word "collecting" and "tracking" in this sentence.
   b. We also question using the term "potential dangers" with controlled substances. Hospice has worked for years to dispel myths associated with narcotic use with terminally ill patients. Please delete terms "POTENTIAL DANGERS" and focus on education on "SAFE USAGE".
   c. Delete discussion or education of controlled substance on initial hospice assessment visit.
3. (c) Standard: Use and maintenance of equipment and supplies
   a. When a hospice contracts for DME isn't it the vendor's responsibility to have repair and routine maintenance policies? And where it is a dealer with a CMS supplier number, can't the hospice assume it meets this requirement since it is a general CMS requirement, too? We recommend the following language*: The hospice, either directly or through contractual agreement, ensures that there is a process for providing routine and preventive maintenance of equipment and that the equipment is safe and works as intended for use in the patient's environment. This may occur directly or through contractual arrangement.* (Addition: "either directly or through contractual agreement" clarifies the responsibilities of contractors if they are used to supply medical equipment.).
   b. Hospices should be required to "write up" unusual occurrences in DME when it happened and report to DME companies.

<u>418.108 Condition of Participation: Short-term inpatient care</u>

a. Define the care as "*care provided by the hospice on an inpatient basis in a facility that meets the requirements of*…and then lists the provider standards in (a) and (b). Then it should say that inpatient care for symptom management and pain control and respite may be provided in any of these facilities. Paragraph (a) should note that pain control and symptom management would be done on an inpatient basis either because of the specific need for the staff and equipment available there or because of the inability of the hospice and/or the patient's caregivers to assure that the services are properly provided in the home. Paragraph (b) would discuss respite and the five-day limit.
b. We are required to train? What authority do we have to train them? Does CMS mean in-service? We are putting them where they will get a higher level of care; in-servicing them on hospice care should be sufficient training.
c. We are supposed to educate hospital staff where we admit our hospice patient. We educate but have no control over them; how can we be held responsible for oversight and can't use that staff more than the patients family members (then why put them in the hospital if the family can do it?? They go inpatient because they have problems we can't even manage at home.
d. Include "psychosocial/family/caregiver crisis" as criteria for inpatient care.

1. (a) Standard: Inpatient care for symptom management and pain control
   a. The word "approved" should be replaced with "certified."
   b. Please clarify the requirements for nursing services for this inpatient level of care. Aren't the proposed regulations changing the requirement for 24 hour RN staffing for the general inpatient level of care as well as respite and replacing it with 24 hour "nursing" care?
   c. Inpatient care must be available for pain control and symptom management and family/caregiver crisis and must be provided in participating Medicare or Medicaid facility.
   d. Respite care must be provided in participating Medicare or Medicaid facility.
   e. 24 RN services available for inpatient care- Respite care does not need 24 hr RN
   f. State specifically that RN services are required in patient level of care, but not for respite care.
2. (b) Standard: Inpatient care for respite purposes
   a. Please define Medicare/Medicaid approved nursing facility. Does this mean, "certified?"
   b. Please clarify the definition of nursing services, i.e. RN, LPN/LVN?
   c. DO NOT require 24 hr/day RN for respite care stays.
3. (c) Standard: In patient care provided under arrangements

a. Please clarify whether or not the hospice is required to have a copy of the patient's entire inpatient clinical record in its possession or whether it can arrange with the inpatient provider to retain the records on its behalf until required. Why require duplication of records if not needed? If a surveyor needed them, they could be requested.
b. Hospices would be able to provide continuity of care by receiving the discharge summary from the hospital and the inpatient record could always be available on request.

<u>418.110 Condition of Participation: Hospices that provide inpatient care directly</u>

a. Include "homelike" in definition.

1. (a) Standard: Staffing
    a. Is it permissible for hospices to ensure the 24-hour coverage in a nursing facility by providing nurses for shifts not covered by the nursing facility? Doesn't this violates the anti-kick back law, and should NOT be allowed.
2. (b) Standard: Twenty-four hour nursing services
    a. There is a general concern that the 24-hour RN requirement has been removed for both the general inpatient levels of care and respite care. Please clarify what "nursing services" means. We suppose that it means services of both RN and LPN/LVN as it does in the NF requirements.
    b. Is there a minimum requirement of services or qualifications?
3. (c)Standard: Physical Environment
    a. Define and provide examples of "equipment failures" that would be required to be reported?
    b. Define what is considered equipment failure that requires repairing. Should be repaired if it results in a <u>serious injury</u> or <u>life-threatening</u>.
4. (f) Standard: Patient Rooms
    a. Please add this to the end of (iv):, *except during community disasters and/or evacuations*
    b. Clarifying how it should be equipped- DEFINE and provide for equipment incorporated into home-like environment.
    c. Space requirements should be omitted from the standard.
5. (l) Standard: Meal Service and menu planning
    a. Thank you CMS for recognizing the nutritional needs of terminally ill patients and also the need for flexibility in this standard.
6. (m) Standard: Pharmaceutical services
    a. Section (m) should also be included in 418.106 as an indication that these are requirements laid on the hospice as a whole, not just on an inpatient basis. (m) Should cross-refer to the earlier standard.
    b. Could you clarify whether or not patients are allowed to bring prescription drugs from home into a facility?
    c. Please add the word "*unpredicted*" before death so that the phrase reads *"regional office any unpredicted death..."*
7. (n) Standard: Pharmacist: 4 Drug Management Procedures
    a. Add "if required by law" to the end of this paragraph.
8. (o) Standard: Seclusion and restraint
    a. The langue in section (o)(i) should be revised to allow hospices to develop evidence-based policies that specify the unique circumstances and interventions of hospice care and the conditions under which they can be implemented r/t restraints. This should be in all settings, not just facilities. Suggested language changes are underlined: <u>Bed rails are not included in this definition of restraint if used for the safety of the patient or to assist the patient in independent functioning.</u> A drug used, as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for a <u>hospice</u> patient's <u>hospice</u> medical or psychiatric condition. Seclusion is the <u>restricted</u> confinement of a person alone in a room or an area where a person is physically prevented from leaving.
    b. Add the word "unpredicted" before death.
    c. Please clarify on (7) as to why this has to be reported to CMS and to what office at CMS.

d. Physician orders for restraints should cover a 24-hour period with the requirement of a nursing assessment every 8 hours to assess the need to continue or discontinue the restraints. The nurse can choose to continue or discontinue and give supporting documentation. Physician orders required every 24 hours.
e. Modify CMS regional office with patient's death cause by strangulation from a restraint.

<u>418.112 Condition of Participation: Hospices that provide hospice care to residents of a SNF/NF, ICF/MR, or other facilities</u>

a. Clarify the term "facility" This section should specifically apply only to Medicare and Medicaid participating facilities. Also, this condition cannot successfully be implemented until there is in the SNF/NF requirements a parallel condition that conforms their requirements. We recommend that the effective date of this section be delayed until the companion section is enacted or that it be at least incorporated by reference into the SNF/NF requirements. We understand that the nursing home COPs will add a section on nursing homes and hospice care. Does this condition match the requirements that will be proposed for nursing homes?
b. We ask that CMS work with surveyors on this issue and that hospices be allowed some leniency until the nursing facility regulations are complete.

1. (b) Standard: Professional management
   a. We would like the word "h*ospice*" inserted before inpatient so the phrase reads "*arrangements necessary for hospice inpatient care...*"
   b. Hospice to be responsible for the coordination of the patient's care. Both hospice and NF regulations should reflect coordination of care between both agencies' services.
   c. Please provide some information regarding how this standard is or is not related to nursing home regulations. We assume that this means that the hospice must avoid making assumptions about care provisions and specify the services to be provided by the facility and the ones to be provided by the hospice and the processes for management and routine communication.
2. (d) Standard: Medical Director
   a. We are concerned that the requirements of this standard may cause unnecessary strain in the relationship between the hospice and the facility. Rather care coordination between members of the hospice IDG and the nursing home team who are likely to have more daily contact with the patient should be encouraged.
   b. Please explain why in this instance (as well as elsewhere in the proposed regulations) the Medical Director appears to be separated out from the rest of the IDT. We believe that the best language would be to require that the IDT assume this duty through a designee of its choice, either an physician or a nurse.
   c. Is it permissible for the NF Medical Director to also be the Hospice Medical Director?
3. (e) Standard: Written agreement
   a. Is the written consent of the patient to be part of the facility/hospice contract?
   b. Clarify a "life threatening" condition other than the patient's hospice terminal diagnosis.
   c. Omit the need for consent to be in the contract with the facility. We have the consent in the individual record.
   d. We are concerned that this does not belong in the written agreement between the hospice and the facility and should be moved to another section.
   e. States vary in what they consider included in the room and board rate and what their responsibility is in the provision of room and board. How does this impact this Standard? Will the room and board definition in the State Operation Manual be changing in relation to the hospice regulations?
   f. Remove (iii) because (i) would ensure that the hospice team is notified of any change which is most important.
4. (f) Standard: Hospice plan of care
   a. We would like a definition or clarification on what is meant by "all caregivers".
   b. Change (f.4) to say, "...any change in the plan of care must be discussed among hospice interdisciplinary team and NF caregivers and must be approved by the interdisciplinary team.

c. We are concerned that this does not belong in the written agreement between the hospice and the facility and should be moved to another section.

5. (g) Standard: Coordination of Services
   a. Are we correct in assuming that "physician orders" refer to the hospice physician orders?
6. (h) Standard: Transfer, revocation, or discharge from hospice care
   a. For some facilities, discharge from the hospice could mean the person may no longer reside in the facility. Please provide some clarification of this standard including how compliance would be audited. Why not change "*does not directly impact*" to "*may not affect*"?
7. (i) Standard: Orientation and training of staff
   a. We are concerned that facilities may be inundated with hospice in-services if they have contracts with multiple hospice providers.

<u>418.114 Condition of Participation: Personnel qualifications for licensed professionals</u>

a. Is the implication here that non-degreed social workers can be hired and work as social workers because they are licensed by the State? If so, the effect of going to State licensure here is to lower the requirement for social workers that has been in this rule up to now. We question whether this is appropriate, given the importance of social workers in this context and we believe CMS should consider reinstating the current requirement.
b. We request that the following language be use: "*All Professionals who furnish services directly, under an individual contract, or under arrangements with a hospice must meet minimum qualifications as specified in paragraph (c) of this section and must be legally authorized (licensed, certified, or registered) to practice by the State in which he or she performs such functions or actions, and must act only within the scope of his or her State license, or State certification, or registration. All personnel qualifications must be kept current at all times.*"

1. (c) Standard: Personnel qualifications when no state licensing, certification, or registration requirements exist.
   a. The minimum qualifications for a hospice social worker should be at least a BSW from a CSWE accredited school of social work. This qualification should take precedence over any state regulation allowing non social work degreed individuals to be licensed as social workers. In addition, the individual with at least a BSW degree from a CSWE accredited school of social work must be licensed according to laws of the state in which the social worker practices. Keep the Condition of Participation as it is currently: "A person who has at least a baccalaureate degree from a school of social work accredited by the Council on Social Work Education."
2. (d) Standard: Criminal background checks
   a. Clarification is needed regarding if criminal background checks are required for volunteers, contract staff, etc.
   b. Hospices should be required to do criminal background checks on all paid staff and patient care volunteers.
   c. Criminal background checks should be the responsibility of the contracted agency per the written agreement.
   d. Another area of concern is the phrase "before employment at the hospice". There should be some flexibility in hospice policy about what the hospice can do with the employee until the results of the background check is returned, if the process in the state is length.

89. Conditions of Participation: Entire Document
   a. Replace the word drugs with medication through out the regulation.
   b. Change "Medicare-approved" to "Medicare certified" throughout COPs.

We appreciate this opportunity to provide comments to CMS regarding the proposed changes in the Conditions of Participation for Hospice. The comments provided are from our members—hospice providers, hospice professionals, and individuals supporting our mission of providing optimum end of life care to the citizens of Illinois. The comments were made to assure quality service to consumers and open access for all to hospice services.

Thank you for your consideration of our comments.

Sincerely,

Harriet O'Connor
President/CEO
Illinois Hospice & Palliative Care Organization